

# Edwards Lifesciences

2022 Annual Report



Edwards



For Sarah Sue Morbitzer,  
it was always going  
to be “game on!”



Sarah Sue was born with Tetralogy of Fallot, and at four months old underwent open-heart surgery to build the wall between her two ventricles and repair two valves. Being the daughter of a high school volleyball coach, Sarah Sue quickly developed a passion for the sport. She lived just 15 minutes away from the Ohio State University and dreamed of one day becoming a volleyball player for the Buckeyes. In 2020, her dream came true. Upon arriving at campus to begin workouts with her teammates, Sarah Sue noticed she was having trouble catching her breath during conditioning. Knowing her heart history, Sarah Sue's athletic trainer sent her to see a cardiologist at the Ohio

State Richard M. Ross Heart Hospital. The cardiologist said she could continue conditioning and practice, but she might need to adjust her workouts and give herself more time for recovery. Not wanting to sit out or slow down, Sarah Sue decided to get her valve replaced over the winter holidays. In December of 2020, she received the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive PreStent. To honor her new valve, Sarah Sue proudly named it Valerie. Just one month later, she played in her first volleyball match wearing scarlet and grey. After two successful seasons, Sarah Sue earned an athletic scholarship at Ohio State.

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*“I always stepped on the court with a lot of heart and passion,  
but after I got my valve, it meant even more.”*

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# A Letter to Our Shareholders

Leading Edwards Lifesciences has been the greatest privilege of my life.

As I look back on the past two decades, I reflect on many of Edwards' extraordinary accomplishments – the development of our life-saving innovations, the strong patient-focused culture we live every day,



and most importantly, the impact we have had on so many patients around the world. I am proud of our talented and dedicated leadership team and our employees who have made all this possible.

The day Edwards became an independent company on April 3, 2000, was exciting, but our future was still uncharted. We were in the very early stages of creating our company and the technologies that would go on to change the lives of so many. Now, 23 years later, I am confident as ever that our future is extremely bright.

While the company and our world have grown and changed since that first day at Edwards, we have never lost sight of why we are here. True to our Credo, which concludes with, “Helping patients is our life’s work, and life is now,” we have stayed focused on our long-term, strategic goals and fostered a patient-focused culture that drives all we do. Impressively, our most recent internal survey found that 93% of our employees consider what is important to patients when making decisions.





### Innovation

Pioneer breakthrough technologies with compelling evidence



### Leadership

Lead groundbreaking standards of care through trusted relationships



### Focus

Singular focus on the large unmet needs of structural heart and critically ill patients

We have continued to partner with clinicians, regulators, hospitals and health systems to bring lifesaving therapies to patients around the world. For example, we have been involved in more than 800,000 transcatheter aortic valve replacement (TAVR) procedures since we pioneered the technology more than a decade ago. We have stayed true to our innovation strategy, even during the pandemic, and have strategically invested in research and development. Our global supply chain has proven resilient, enabling us to meet physician and patient needs. We have also continued to grow our talented and dedicated employees – now stronger than 17,000 worldwide, including more than 2,000 engineers.

It is gratifying to reflect on all we have achieved together, but I also know Edwards is just getting started. We have a leadership team with unmatched experience who shares my commitment to patients. We have worked cohesively for many years, collaborating on Edwards’ strategy, and I am certain the company will continue to build on our legacy of patient impact, innovation and growth.

It is this confidence that underpins my decision to retire in May of this year and step into a different role at Edwards. I feel proud of the planful transition that the Board and I have mapped out. I know that my successor, Bernard Zovighian, is as right for this new role as he was to lead our successful Transcatheter Mitral and Tricuspid Therapies (TMTT) business and, before that, Surgical Structural Heart (where it all began for Edwards). He cares deeply about patients, our employees and our company. He brings to the job a strong strategic mindset, deep experience in innovation and passion for establishing trusted partnerships.

### Culture and Strategy Led

The strong culture and patient-focused strategy we have at Edwards requires establishing critical partnerships based on mutual trust. It requires an

emphasis on quality, integrity and transparency. It requires talented employees who are committed to patients, who think creatively and who are dedicated to lifelong learning. This in turn requires a workplace where our employees feel they belong, where they enjoy and value their work, and where they can be their best.

Through the commitment to our strategy, we are continuing to generate high-quality scientific evidence to demonstrate that our life-saving technologies lead to substantial health and economic benefits.

### Innovation Prioritized

Our leading therapies continue to transform patient care around the world. To help more patients and further strengthen our long-term leadership position, we continue to invest in research and development at a significant rate of 17-18% of sales.

While many companies in our industry try to grow through diversification and acquisitions, we have stayed committed to organic growth through innovation in structural heart and critical care.

We have considerable research underway to demonstrate the value of our innovative technologies and hopefully expand the number and type of patients who benefit from those technologies. As an example, under current rules, most people receive treatment when they are diagnosed with a disease, but many patients with heart valve failure are not eligible to receive treatment until they display symptoms. Our pivotal trial, EARLY TAVR, is studying the treatment of severe aortic stenosis (AS) patients before debilitating symptoms appear and may help us to determine if there are dangers associated with waiting to treat these patients. In addition, enrollment is continuing in PROGRESS, a pivotal trial studying the treatment of patients with moderate AS.

The global TAVR market will continue to be driven by greater awareness and advances in new technologies, as well as indication expansions and increased global adoption. We expect to help twice as many TAVR patients by 2028.



In the face of systemic tensions that delay or deny treatment to older patients alongside hospital staffing challenges and patients reluctant to seek care, we have also taken on several initiatives to ensure that heart patients get the care they need. And we are encouraged by how organizations like the American Heart Association are engaging to help improve the quality of care delivery for patients who need it.

In TMTT, we are transforming treatment for patients with severe mitral and tricuspid valve disease. To do this, we need differentiated therapies, positive clinical trial results to support approvals and adoption, and a strong partnership with clinicians to produce real-world clinical outcomes.

Clinical experience with our therapies is showing important progress in addressing the unmet needs of these patients. We recently shared positive results from the TRISCEND study of our EVOQUE transcatheter tricuspid valve replacement system. We aim to achieve approvals for the EVOQUE system in Europe this year and in the U.S. by the end of 2024. We are pleased to see continued adoption of the PASCAL repair system in Europe and the U.S. with more than 10,000 patients who have now been treated with PASCAL.

In our Surgical business, we are advancing our leadership by identifying and solving critical unmet patient needs in cardiac surgery. In 2022, we received FDA approval to introduce our MITRIS RESILIA valve. We will also continue to broaden the adoption of our flagship surgical aortic heart valve, INSPIRIS RESILIA, which is changing the standard of tissue durability in cardiac surgery.

In Critical Care, we have improved the quality of care for more than 16 million patients by creating new technologies, expanding clinical evidence and driving adoption. We continue to evolve our hemodynamic monitoring platform, which uses machine learning to help clinicians predict and prevent hypotension. We recently introduced connectivity to this monitoring platform to allow clinicians to access their patients' continuous blood pressure data on their smartphones.

We believe our opportunity to serve structural heart and critical care patients will nearly double to \$20 billion by 2028.

## Committed Corporate Citizens

The Edwards Lifesciences Foundation has focused on supporting programs designed to treat underserved people to reduce heart valve disease, to strengthen the communities where Edwards' employees live and work

and to promote employee volunteerism. We also aspire to have all our employees engage in charitable efforts that are meaningful to them, and I am proud to share that the great majority did so in 2022. Our signature initiative, *Every Heartbeat Matters*, is focused on improving the lives of an additional 2.5 million underserved structural heart and critical care patients by the end of 2025.

Sustainability, ethical behavior, supporting community health, and fair and inclusive practices are part of everything we do at Edwards. Our commitment to environmental, social and governance (ESG) practices continue to lead to numerous awards and recognitions, including the Dow Jones Sustainability World Index for the third year in a row. While we are honored to receive accolades, this is not the reason we embrace ESG practices. We do so because it's core to our credo and behaving as a trusted partner is part of our values.

## Strong Global Performance During a Challenging 2022

Though 2022 was still a challenging year for hospitals and health systems – which had an impact on our business – the lingering effects of the pandemic are dissipating, as hospitals rebuild staffing capacity, and more heart patients seek care. We have also partnered with clinicians and hospitals to optimize TAVR programs, leading to significant reductions in the length of procedures and hospital stays, as well as the number of staff needed for the procedure.

In 2022, our company grew eight percent on a constant currency basis versus 2021. Our 2022 adjusted earnings per share grew 12 percent. Our results fell short of our expectations and were primarily impacted by hospital staffing shortages around the globe, and foreign currency rates that moved significantly during the year.

We received regulatory approvals to introduce our industry-leading SAPIEN 3 Ultra RESILIA valve in the U.S., Japan and other key geographies around the world, and we are proud we have seen strong adoption of this valve in both countries. RESILIA tissue now serves as the platform for Edwards' new class of valves. A recent study showed positive results for RESILIA tissue at five years and provides the potential to extend the durability of all of our valves.

Our next generation PASCAL Precision mitral repair system received approval in Europe and early approval in the U.S. to treat patients suffering from degenerative mitral regurgitation.



Our innovative therapies and development will continue to drive strong organic growth in the years to come, as will our initiatives to improve patient access to life-saving care.

## Looking to the Future

I feel strongly that Edwards' best days are ahead, and the company will thrive and grow with Bernard as CEO. Aside from his already impressive skills and decades of medtech experience, including eight years here at Edwards, he will be supported by our expert, highly engaged board of directors, as well as our stellar executive team. At the annual meeting in May, I will

stand for election as non-executive chairman of Edwards' Board, and I look forward to my continued engagement in this role.

To our employees, I want to thank you, again, for everything that you do for our company and for patients around the world. It has truly been my greatest honor to be Edwards' CEO and I look forward to supporting Edwards for years to come.

Sincerely,



**Michael A. Mussallem**

Chairman & Chief Executive Officer



## More About Bernard

Bernard J. Zovighian is president of Edwards Lifesciences, and will become CEO of the company in May 2023. In his time as president, he is working closely alongside Mike Mussallem in engagement with Edwards' board of directors, executive leadership team, worldwide employees and other

stakeholders to further Edwards' patient-focused innovation strategy. Prior to this leadership transition, Zovighian served since January 2018 as corporate vice president responsible for the company's Transcatheter Mitral and Tricuspid Therapies (TMTT) business. As the leader for TMTT, Zovighian established a global

organization focused on developing and delivering a portfolio of therapies designed to change the standard of care for mitral and tricuspid patients. Zovighian joined Edwards Lifesciences in January 2015 as vice president and general manager of the Surgical Structural Heart business, later serving as corporate vice president of the surgical business from 2016 until he began leading TMTT. Prior to joining Edwards, Zovighian held a variety of roles with increasing levels of responsibility at Johnson & Johnson (J&J) for nearly 20 years, in roles such as regional leadership outside of the United States and worldwide president of one of the company's divisions. He has dual master's degrees in science and business from Universities of Marseille, France.

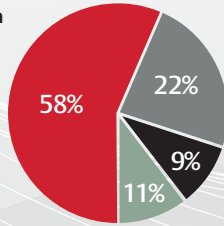
This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. Statements 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 2023 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. These risks and uncertainties include, but are not limited to: our success in developing new products and avoiding manufacturing and quality issues; clinical trial or commercial results or new product approvals and therapy adoption; the impact of public health crises, including the COVID-19 pandemic; the impact of domestic and global economic conditions; competitive dynamics in the markets in which we operate; our reliance on vendors, suppliers, and other third parties; damage, failure, or interruption of our information technology systems; consolidation in the healthcare industry; our ability to protect our intellectual property; our compliance with applicable regulations; our exposure to product liability claims; use of our products in unapproved circumstances; changes to reimbursement for our products; the impact of currency exchange rates; unanticipated actions by the United States Food and Drug Administration and other regulatory agencies; changes to tax laws; unexpected impacts or expenses of litigation or internal or government investigations; and other risks detailed under "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.

Caution: In the U.S., EVOQUE and SAPIEN M3 are investigational devices and are not commercially available.

# 2022 Highlights

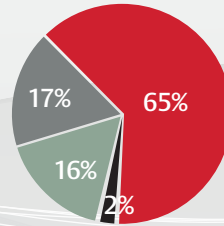
2022 Sales by Geographic Region

- United States
- Europe
- Japan
- Rest of World

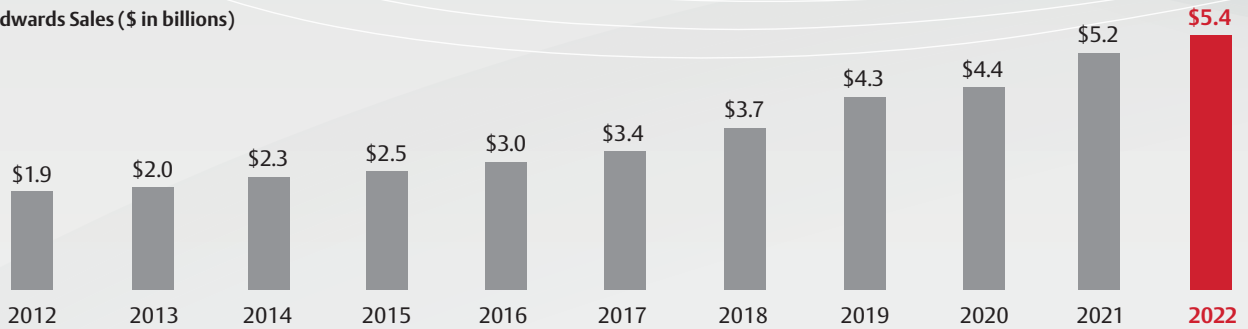


2022 Sales by Product Line

- TAVR
- Surgical
- Critical Care
- TMTT



Edwards Sales (\$ in billions)



**800K+** patients treated with transcatheter technologies



**2,000+** engineers



**17,000+** global employees



**8%** underlying sales growth

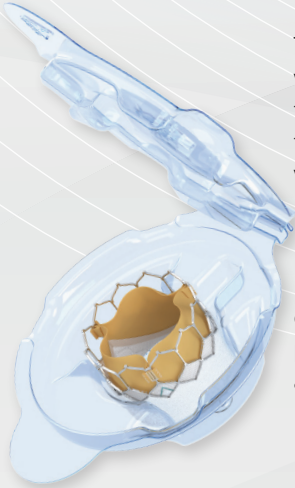


**12%** adjusted EPS growth



## Transcatheter Aortic Valve Replacement

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 an approved treatment option for all Severe Symptomatic Aortic Stenosis patients including those at low risk to surgery in Europe, the US, Japan and other countries around the world based on the superiority of outcomes demonstrated in the PARTNER 3 Trial. Building on the benefits of the SAPIEN 3 platform, the SAPIEN 3 Ultra valve with RESILIA tissue technology is now available in the US and Japan.



**Edwards SAPIEN 3 Ultra RESILIA** transcatheter heart valve

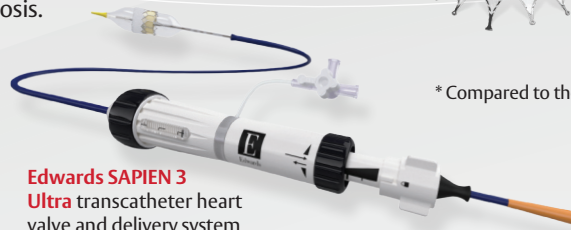
The Edwards SAPIEN 3 Ultra transcatheter heart valve system with RESILIA tissue is built upon the proven SAPIEN platform featuring the same tissue technology used in the leading surgical valve in the US, a ~40 percent taller\*, textured outer skirt designed to further reduce paravalvular leak.

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.

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



**Alterra** adaptive prenent and **SAPIEN 3** transcatheter heart valve



**Edwards SAPIEN 3 Ultra** transcatheter heart valve and delivery system

\* Compared to the Edwards SAPIEN 3 valve.

## Transcatheter Mitral & Tricuspid Therapies

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

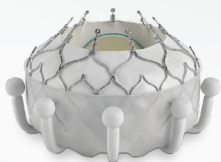


**Edwards PASCAL** repair system

Our PASCAL repair platform delivers differentiated transcatheter leaflet repair for patients with mitral and tricuspid regurgitation. Through continuous innovation coupled with our high touch procedural and imaging support, the PASCAL system enables our physician partners to optimize clinical outcomes for their patients.

The EVOQUE tricuspid replacement system expands our treatment options for patients with tricuspid valve disease, providing a new transcatheter therapy for patients with limited options today. SAPIEN M3 and EVOQUE Eos mitral valve replacement systems are designed to treat patients with mitral valve disease. We are advancing our clinical experience with these mitral and tricuspid replacement therapies through continued enrollment in pivotal trials and clinical studies.

\* Investigational device. Limited to investigational use only.



**Edwards EVOQUE\*** tricuspid replacement system



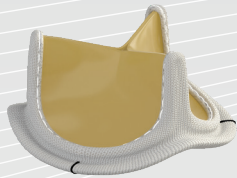
**Edwards Cardioband\*\*** tricuspid reconstruction system

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

\*\* CE Mark in EU. Investigational device and not available for sale in the US.

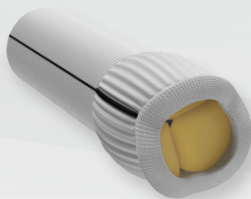
## Surgical Structural Heart

Edwards Lifesciences has a proven commitment to ongoing innovation in surgical structural heart solutions, to advance the state of the art and put better outcomes within reach. Today's RESILIA tissue portfolio represents the best of creative scientific minds coming together to address the unmet needs and satisfy patient demands for better surgical options.



**INSPIRIS RESILIA**  
aortic valve

The market-leading 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. Unlike other valves, the INSPIRIS valve is specifically designed to deliver a controlled and predictable expansion during valve-in-valve deployment, providing a patient lifetime management solution for the surgeon.



**KONNECT RESILIA**  
aortic valved conduit

KONNECT RESILIA aortic valved conduit is 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.



**MITRIS RESILIA**  
mitral valve

The MITRIS RESILIA mitral valve is built on the trusted Carpentier-Edwards PERIMOUNT valve platform with RESILIA tissue and an enhanced delivery experience. Cobalt chromium bands

provide good visibility under fluoroscopy for easy identification of the landing zone for potential future transcatheter interventions.

This valve handles the pressure of the mitral position and allows patients to live without the quality-of-life compromises required with mechanical valves.

## Critical Care

Edwards is the leader in smart hemodynamic monitoring solutions including monitoring platforms, predictive software, and sensors ranging from invasive to noninvasive, all of which play an important role in patient recovery. This portfolio of advanced hemodynamic solutions helps clinicians make proactive decisions for individualized patient care. All monitoring solutions are offered on our HemoSphere monitor, which brings pressure, flow, and tissue oximetry to a single screen.



**HemoSphere** advanced monitoring platform with HPI software

Acumen Hypotension Prediction Index software is a first-of-its-kind predictive software developed with machine learning. It detects hemodynamic instability and hypotension up to 15 minutes before it occurs and enables clinicians to prevent or treat hypotension. Hypotension is associated with post-operative complications including acute kidney injury and myocardial injury.

Acumen Assisted Fluid Management software is our second software developed with machine learning. This software predicts if a patient is fluid responsive, and is designed to help keep patients in the optimal fluid range.

Our latest Smart Recovery solutions, such as Acumen IQ sensor and Acumen IQ noninvasive finger cuff, unlocks our predictive software and provide clinicians advanced hemodynamic

parameters and decision support to help them stay ahead of their patient's rapidly evolving status.



**ForeSight Elite**  
tissue oximetry sensor

Our ForeSight tissue oximetry sensor helps clinicians monitor for low oxygen levels in the brain or tissue, which can cause significant complications if left untreated. With the edition of ForeSight sensor to our HemoSphere monitor, Edwards became the first to offer clinicians the ability to monitor the heart and the brain from one screen.



**Acumen IQ**  
finger cuff



**Acumen IQ**  
sensor



## Our Aspirations – The Heartbeat of Edwards

At Edwards, our Credo defines our culture, strategic priorities, and our vision for sustainability and long-term value creation. Our environmental, social and governance (ESG) or sustainability goals are closely aligned with our corporate aspirations and are intended to address those topics that have been assessed to be of the most importance to Edwards and its stakeholders.

### Transforming patient lives with breakthrough medical technologies



Edwards is driven by a passion to help patients, partnering with clinicians to develop innovative technologies in the areas of structural heart disease and critical care monitoring. We put patients first, working to produce better technologies that enable better outcomes for patients.

### Excelling as a trusted partner through distinguished quality and integrity



Edwards conducts business ethically and with integrity, providing the highest level of care and respect for our partners. We are committed to the quality and safety of our products, driving innovation and promoting resource efficiency.

### Fostering an inclusive culture where all employees grow and thrive



Fulfilling our mission to help patients requires a strong, healthy and talented workforce. Edwards recruits top candidates, offers employee wellness and engagement programs and fosters a diverse and inclusive culture to help employees deliver their best.

### Passionate engagement that strengthens our communities



Edwards is committed to strengthening the health of our global communities. With patients as our top priority, we work to increase access to our innovative therapies, improve efficiency of healthcare processes, improve awareness of and treatment for life-threatening diseases and provide opportunities for our employees to give back.

### Delivering exceptional shareholder value



Through all of our sustainability initiatives and delivering on our focused company strategy, Edwards is positioned for long-term profitability that will benefit our stakeholders and also our bottom line.





**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.



## 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*



## 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 and sales growth information, which excludes currency exchange rate fluctuations, the conversion to a consignment inventory system for surgical structural heart (“Surgical”), and the positive impact of transcatheter aortic valve replacement (“TAVR”) stocking sales in Germany and the negative impact of de-stocking. The Company uses the term “adjusted” to also exclude intellectual property litigation expenses, fair value adjustments to contingent consideration liabilities arising from acquisitions, amortization of intangible assets, a significant program discontinuation, significant charges associated with TAVR inventory write offs, the conversion to a consignment inventory for Surgical, the positive impact of TAVR stocking sales in Germany and the negative impact of de-stocking, impairment of long-lived assets, pension curtailment gains, 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 currency 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)	2022	2021	2020	2019	2018
<b>GAAP Net Sales</b>	<b>\$5,382.4</b>	\$5,232.5	\$4,386.3	\$4,348.0	\$3,722.8
Impact of Surgical consignment	–	–	–	–	82.5
Impact of Germany stocking	–	–	–	–	8.0
<b>Adjusted Net Sales</b>	<b>\$5,382.4</b>	\$5,232.5	\$4,386.3	\$4,348.0	\$3,813.3

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)	2022	2021	2020	2019	2018
<b>GAAP Net Income</b>	<b>\$1,521.9</b>	\$1,503.1	\$823.4	\$1,046.9	\$722.2
Non-GAAP adjustments:					
Intellectual property litigation expenses, net	11.9	15.5	28.5	25.2	26.4
Change in fair value of contingent consideration liabilities, net	(35.0)	(121.6)	12.3	(7.1)	(8.0)
Amortization of intangible assets	4.8	6.9	4.6	4.0	2.4
Program discontinuation	47.0	–	–	–	–
Litigation settlement	–	–	305.1	–	137.5
TAVR inventory write off	–	–	–	55.2	–
Surgical consignment conversion	–	–	–	–	54.7
TAVR Germany stocking sales	–	–	–	–	4.7
Impairment of long-lived assets	–	–	–	40.6	109.3
Pension curtailment gain	–	–	–	–	(6.3)
Purchased in-process research and development	–	–	–	18.1	–
Impact from U.S. tax legislation	–	–	–	–	(2.5)
Tax audit settlements	–	–	–	–	(36.1)
<b>Adjusted Net Income</b>	<b>\$1,550.6</b>	\$1,403.9	\$1,173.9	\$1,182.9	\$1,004.3

## Reconciliation of GAAP to Adjusted Diluted Earnings Per Share

<b>GAAP Diluted Earnings Per Share</b>	<b>\$2.44</b>	\$2.38	\$1.30	\$1.64	\$1.13
Non-GAAP adjustments:					
Intellectual property litigation expenses, net	0.03	0.02	0.05	0.04	0.04
Change in fair value of contingent consideration liabilities	(0.06)	(0.19)	0.02	(0.01)	(0.01)
Amortization of intellectual property	–	0.01	0.01	0.01	–
Program discontinuation	0.07	–	–	–	–
Litigation settlement	–	–	0.48	–	0.21
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
Pension curtailment gain	–	–	–	–	(0.01)
Purchased in-process research and development	–	–	–	0.03	–
Tax audit settlements	–	–	–	–	(0.06)
<b>Adjusted Diluted Earnings Per Share</b>	<b>\$2.48</b>	\$2.22	\$1.86	\$1.86	\$1.57

## Adjusted Free Cash Flow

Twelve months ended December 31 (in millions)	2022	2021	2020	2019	2018
Net cash provided by operating activities	\$1,218.2	\$1,732.1	\$1,054.3	\$1,182.9	\$926.7
Capital expenditures	(244.6)	(325.8)	(407.0)	(254.4)	(238.7)
Litigation settlements	–	–	86.4	138.3	–
Tax audit settlement	–	–	–	–	56.7
Repatriation tax payments	–	–	–	–	41.0
<b>Adjusted Free Cash Flow</b>	<b>\$973.6</b>	\$1,406.3	\$733.7	\$1,066.8	\$785.7

## Adjusted Net Sales Growth

Twelve months ended December 31	2022	2021	2020	2019	2018
<b>GAAP Net Sales Growth Rate</b>	<b>2.9%</b>	19.3%	0.9%	16.8%	8.4%
Impact of Surgical consignment	0.0%	0.0%	0.0%	(2.5%)	2.4%
Impact of Germany stocking	0.0%	0.0%	0.0%	(0.3%)	0.3%
Impact of CASMED acquisition	0.0%	0.0%	0.0%	(0.5%)	0.0%
Impact of foreign exchange	4.8%	(1.5%)	(0.3%)	1.8%	(1.1%)
<b>Adjusted Net Sales Growth Rate</b>	<b>7.7%</b>	17.8%	0.6%	15.3%	10.0%

Note: Numbers may not calculate due to rounding.

**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, 2022

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:

<u>Title of each class</u>	<u>Trading Symbols(s)</u>	<u>Name of each exchange on which registered:</u>
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 .

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recover analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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, 2022 (the last trading day of the registrant's most recently completed second quarter): \$58,453,646,002 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, 2023, was 608,313,396.

**Documents Incorporated by Reference**

Portions of the registrant's proxy statement for the 2023 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2022) are incorporated by reference into Part III, as indicated herein.



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**EDWARDS LIFESCIENCES CORPORATION**  
**Form 10-K Annual Report—2022**  
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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. Statements other than statements of historical or current 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, the expected impact of macroeconomic conditions on our business, any predictions, opinions, expectations, plans, strategies, objectives and any statements of assumptions underlying any of the foregoing relating to the our 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: our success in developing new products and avoiding manufacturing and quality issues; clinical trial or commercial results or new product approvals and therapy adoption; the impact of public health crises, including the COVID-19 pandemic; the impact of domestic and global economic conditions; competitive dynamics in the markets in which we operate; our reliance on vendors, suppliers, and other third parties; damage, failure, or interruption of our information technology systems; consolidation in the healthcare industry; our ability to protect our intellectual property; our compliance with applicable regulations; our exposure to product liability claims; use of our products in unapproved circumstances; changes to reimbursement for our products; the impact of currency exchange rates; unanticipated actions by the United States Food and Drug Administration and other regulatory agencies; changes to tax laws; unexpected impacts or expenses of litigation or internal or government investigations; 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 United States 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.

### WEBSITE REFERENCES

In this Annual Report on Form 10-K, we make references to our website at [www.edwards.com](http://www.edwards.com). References to our website through this Form 10-K are provided for convenience only and the content of our website does not constitute a part of, and shall not be deemed incorporated by reference into, this Annual Report on Form 10-K.

## **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 our field 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 cardiac surgeon 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 (typically an interventional cardiologist) 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**

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](http://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 aortic heart valves. The *Edwards SAPIEN* family of valves, including *Edwards SAPIEN XT*, the *Edwards SAPIEN 3*, the *Edwards SAPIEN 3 Ultra*, and the *Edwards SAPIEN 3 Ultra RESILIA* transcatheter 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 aortic 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% of our net sales in each of 2022, 2021, and 2020, respectively.

### ***Transcatheter Mitral and Tricuspid Therapies***

We continue to make 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 development and clinical phases, the *PASCAL PRECISION* and *Cardioband* transcatheter valve repair systems are commercially available in Europe for mitral and tricuspid valve repair. As of 2022, the *PASCAL PRECISION* system is also commercially available in the U.S. for degenerative mitral regurgitation patients. The *PASCAL PRECISION* system addresses the needs of patients with mitral or tricuspid regurgitation through leaflet approximation, while the *Cardioband* system enables clinicians to reduce the valve’s annulus and lower regurgitation. In addition to transcatheter repair, we believe transcatheter replacement is key to unlocking the full mitral and tricuspid opportunity. We believe our two-platform mitral replacement strategy positions us for leadership in the mid-to-long term. *SAPIEN M3* is based on the proven *SAPIEN* valve while *EVOQUE Eos* is designed specifically for mitral patients. For tricuspid valve replacement, our *EVOQUE* system is also sub 30-French, and available in a variety of valve sizes to enable treatment in a wide range of patient anatomies.

### ***Surgical Structural Heart***

We are innovating in the field of cardiac surgical therapies to improve the quality of life for patients. Our *RESILIA* tissue, with published clinical data showing 0% structural valve deterioration through five years<sup>1</sup>, is helping us redefine tissue durability standards. Our latest innovation, the *INSPIRIS RESILIA* aortic valve, is built on our *PERIMOUNT* platform, offering *RESILIA* tissue and *VFit* technology. *INSPIRIS* is the leading aortic surgical valve in the world. Sales of our surgical therapies in the United States also continue to gain traction with *KONECT RESILIA*, the first pre-assembled, aortic tissue valved conduit.

The *MITRIS RESILIA* valve, our newest mitral valve incorporating our latest tissue technology, is now commercially available in both the U.S. and Japan. We believe the demand for surgical structural heart therapies is growing worldwide, and that our innovation strategy will continue to strengthen our leadership and positive impact on patients.

<sup>1</sup> Bavaria, et al. Five-year Outcomes of the COMMENCE trial investigating Aortic Valve Replacement with a Bioprosthetic Valve with a Novel Tissue. The Society of Thoracic Surgeons 2021 Annual Meeting; Bartus, et al. Final 5-year outcomes following aortic valve replacement with *RESILIA* tissue bio prosthesis. European Journal of Cardio-Thoracic Surgery, 2020.

Sales of our surgical tissue heart valve products represented 15%, 15%, and 16% of our net sales in 2022, 2021, and 2020, respectively.

### **Critical Care**

We are the world leader in advanced hemodynamic monitoring systems used to measure a patient's heart function and fluid status in surgical and intensive care settings. Edwards' complete hemodynamic portfolio helps clinicians make proactive clinical decisions that can improve patient recovery. The portfolio includes the minimally-invasive *FloTrac* and *Acumen IQ* sensors, the noninvasive *ClearSight* and *Acumen IQ* cuffs, and the *ForeSight* noninvasive tissue oximetry sensor. We also support clinical needs with our well-established *Swan-Ganz* pulmonary artery catheters and arterial pressure monitoring products. Compatible with our portfolio of sensors and catheters, the *HemoSphere* monitoring platform displays valuable physiological information. Our first predictive algorithm, *Acumen Hypotension Prediction Index* software, alerts clinicians in advance of a patient developing dangerously low blood pressure. Our latest algorithm, *Acumen Assisted Fluid Management* software, provides patient-specific fluid suggestions to help keep patients in an optimal range during surgery.

### **Competition**

The medical technology industry is highly competitive. We compete with divisions of larger companies as well as smaller companies that offer competitive product lines in certain geographies in which we operate. We also compete with both established and newer technologies that target the patients served by our products. 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 believe we hold leadership positions because we develop and produce safe and effective therapies supported by rigorous clinical studies with extensive data and with 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 Artivion, Inc (formerly 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, a subsidiary of Masimo Corporation.

### **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 2022.

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 2022, 58% of our net sales were derived from sales to customers in the United States.

**Outside of the United States.** In 2022, 42% of our net sales were derived outside of the United States through our direct sales forces and independent distributors. Of the total sales outside of the United States, 52% were in Europe, 21% were in Japan, and 27% were in Rest of World. We sell our products in approximately 100 countries, including Japan, Germany, France, United Kingdom, Italy, China, and Canada. A majority of the sales and marketing approach outside of 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 the Dominican Republic and Puerto Rico.

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 quality products to our patients 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 uses 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 2022, 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 5% year over year, representing 18% of 2022 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. 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.

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 United States and in foreign countries. We continue to innovate and file new patent applications to protect our new products and technologies.

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

### **Government Regulation and Other Matters**

Our products and facilities are subject to regulation by numerous government agencies, including the FDA, European 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, including, but not limited to, those regulating employee health and safety, labor, competition, trade secret, 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.

***Regulation Outside of the United States.*** Outside of the United States, the regulation of medical devices is complex. In Europe, our products are subject to extensive regulatory requirements. The regulatory regime in the European Union (“EU”) 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 EU’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 EU 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 EU implemented a new regulatory scheme for medical devices under the Medical Device Regulation (“MDR”). The MDR became effective on May 26, 2021 and brought 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”). 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***

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 routinely engages with leadership to review and discuss our human capital management (“HCM”), with time dedicated at each regularly scheduled meeting to discuss talent management, which include topics such as talent strategy, diversity, succession planning, employee development, employee health, safety, and welfare, results of employee surveys, and compensation. Our Board of Directors also annually approves the strategic talent imperatives that are tied to our Key Operating Drivers (“KODs”). Our KODs are tracked using a point system across our entire organization that focus the Company and management toward short-, medium-, and long-term goals. The strategic talent imperatives are developed to identify talent related initiatives that support achievement of the KODs.

In addition, the Chief Executive Officer (“CEO”) and his leadership team have talent management related performance goals tied to their compensation; these Performance Management Objectives are reviewed on an annual basis, tracked, and then reported to and evaluated by our Board of Directors.

As we scale to reach more patients around the world, we have integrated our Talent & Organization (“T&O”) Strategy with our Edwards Strategic Planning process. The purpose of our T&O Strategy is to anticipate dynamic global trends related to our workforce, develop our talent to meet future organizational needs, and enable us to be well-poised to meet these needs. Our T&O Strategy enables us to explore external workforce signals, share insights, and identify and build emerging capabilities across our organization. This has enabled us to build a comprehensive succession planning process that allows us to build strong talent from within while we pursue an aggressive recruiting process to fill any gaps with highly qualified external talent. This consistent and scalable approach looks across all our product groups, regions, and significant functions to align and elevate priorities, critical capabilities, and organizational evolutions in line with our strategic plan. This integrated approach informs our yearly objectives and fuels our talent roadmap across the strategic horizon.

Our HCM governance includes a global talent development review (“TDR”) process 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. We track our performance regularly.

### ***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 an ethical culture where we celebrate diversity, promote good health and safety, empower employees to speak up, and ensure that employees’ voices are heard. We strive to offer competitive employee well-being 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.

### ***Diversity, Inclusion, and Belonging***

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 have established a Diversity, Inclusion, and Belonging strategy that includes our four focus areas of Business, People, Communication, and Community, and whose overriding priority is “The Patient.” As a practice, all employees receive unconscious bias training as a foundational aspect of our culture.



### ***Employee Listening***

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 gain employees' feedback in a confidential manner. The CEO and Executive Leadership Team hold themselves accountable to act on the results of the survey, and these results are reviewed by management with our Board of Directors. This initiative helps us gain insights on various topics including patient focus, diversity, inclusion and belonging, quality, innovation, engagement, as well as a sense of support at all levels of the organization. Speak-Up is a resource available to all employees to bring forth compliance related concerns; a key element of our compliance program is that each employee is accountable for maintaining ethical business practices. In addition, during each quarterly townhall meeting, our CEO 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.

### ***Total Well-being***

We understand that good health leads to better performance. We offer competitive employee well-being packages that include, among other things, health and wellness insurance, health savings accounts, family support services, and a variety of site-specific programs. We regularly evaluate our well-being package to make modifications that are aligned with the competitive landscape, legislative changes, and the unique needs of our population. We also provide robust well-being programs that address prevention, nutrition, mental health, physical activity, financial fitness, and community service. In recent years, mental well-being has become a central topic for organizations worldwide. As part of our regular evaluation and commitment to putting employees first, we launched a new program, Mind+, which offers a wide variety of mental well-being programs for our employees. This commitment extends to creating a work environment where employees can feel confident speaking about mental well-being with their managers and know how best to access the tools and resources available to support them. We believe there are strong benefits when employees are feeling their best. Employees who are mentally healthy are more innovative, resilient, better decision-makers, and able to build stronger relationships. We also believe that prioritizing and promoting Mind+ allows us to help patients around the world to live longer, healthier, and more productive lives and supports employees to be their best self at home and at work.

### ***Talent Development***

Edwards has established a long-term aspiration to grow and develop talent significantly, centering our efforts around critical leadership and technical skills for the present and future needs of the business. Our learning and development structure and processes strive to meet the internal demand to develop our talent in such a way that demonstrates impact at scale and delivered to our workforce through optimized learning modalities. This includes leadership training programs, including our ethical decision making training program for managers.

### ***Headcount and Labor Representation***

As of December 31, 2022, we had approximately 17,300 employees worldwide, the majority of whom were located in the United States, Singapore, the Dominican Republic, and Costa Rica. 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](http://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. Please note that the headers and summary provided below are only intended to assist the reader in navigating the risk factors; some risks, present or future, may implicate multiple types of risks. Please read all risk factors in their entirety.*

### **Summary of Risk Factors**

We group our risk factors into three principal sections: (1) Business and Operating Risks; (2) Market and Other External Risks and (3) Legal, Compliance and Regulatory Risks. The following summarizes the principal risks and uncertainties affecting our business, financial condition, and results of operations. This summary should not be relied upon as an exhaustive summary of the material risks facing our business and you should read this summary together with the more detailed description of risks and uncertainties discussed below.

#### **Business and Operating Risks**

- Failure to successfully innovate and market products
- Unsuccessful clinical trials or procedures
- Manufacturing, logistics, or quality problems
- Public health crises, including pandemics and epidemics
- Competition
- Dependence on key physicians and research institutions
- Reliance on vendors, suppliers, and other third parties
- Damage, failure, or interruption of our information technology systems, including due to cyber-based attacks and breaches
- Failure to recruit and retain qualified talent or execute management succession plans
- Underperforming operations or unsuccessful business acquisitions or strategic alliances

#### **Market and Other External Risks**

- Risks associated with international sales and operations
- Inability to obtain government reimbursement or reductions in reimbursement levels
- Industry consolidation

#### **Legal, Compliance and Regulatory Risks**

- Inability to protect our intellectual property
- Inability to defend against intellectual property claims from third parties
- Compliance with government regulations

- Losses from product liability claims
- Use of products in unapproved circumstances
- Substantial costs from environmental, health and safety regulations
- Climate change
- Regulatory actions relating to animal borne illnesses

**Business and Operating Risks**

***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 because of the introduction of a competitor's newer technologies or changing customer preferences. 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 successfully market them could be constrained by a number of different factors, including competitive products and pricing, 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, and any such delay, suspension, or termination could have a material adverse effect on our prospects or the market's view of our future prospects.

***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, cyber incidents, 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 partners 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 are subject to risks associated with public health crises, including the COVID-19 pandemic and other pandemics or epidemics.***

We are subject to risks associated with public health crises, including the global health concerns related to the COVID-19 pandemic. The 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 operations and the operations of our customers, suppliers, and business partners. Other public health crises, including any future epidemics or pandemics, could result in similar adverse impacts on our business and markets. Financial or operational impacts that we have experienced in connection with the COVID-19 pandemic and may experience as a result of future COVID-19 outbreaks or other public health crises include:

- Staffing shortages at hospitals which can add to the barriers along the patient treatment pathway;
- Impacts and delays to clinical trials, our pipeline milestones, or regulatory clearances and approvals;
- 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; or
- Significant volatility or reductions in demand for our products.

Depending on the severity of the financial and operational impacts, our business, financial condition, and results of operations may be materially adversely impacted. The extent to which the COVID-19 pandemic or other future public health crises may impact our business, results of operations, and financial condition depends on many factors which are highly uncertain and are difficult to predict. These factors include, but are not limited to, the duration and spread of any outbreak, its severity, the actions to contain or address the impact of the outbreak, the timing, distribution, and efficacy of vaccines and other treatments, United States and foreign government actions to respond to possible reductions in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume.

***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 technologies of many types and 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.

***The success of many of our products depends upon certain key physicians and research institutions.***

We work with leading global physicians and research institutions who 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 with the research institutions of which they are a part or to continue to receive their advice and input or we are otherwise unsuccessful in maintaining strong working relationships with these physicians or their research institutions, 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.

***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 experience from time to time, and may continue to 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 or supply medical technology companies, including due to the burdens of applicable quality requirements and regulations or for no reason at all;
- The limitation or ban of certain chemicals or other materials used in the manufacture of our products; and
- Delays or shortages due to trade or regulatory embargoes.

Additionally, any significant increases in the cost of raw materials, whether due to inflationary pressure, supply constraints, regulatory changes, or otherwise, could adversely impact our operating results. 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 or at all, which could have a material adverse effect on our business.

***Failure to protect our information technology infrastructure and our products 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, and data corruption.

In addition, our information technology infrastructure and products are vulnerable to cyber-based attacks. Cyber-based attacks can include, but are not limited to, computer viruses, denial-of-service attacks, phishing attacks, ransomware attacks, and other introduction of malware to computers and networks; unauthorized access through the use of compromised credentials; exploitation of design flaws, bugs, or security vulnerabilities; intentional or unintentional acts by employees or other insiders with access privileges; and intentional acts of vandalism by third parties and sabotage. In addition, United States federal and state laws and regulations, and the laws and regulations of jurisdictions outside of the United States, such as the General Data Protection Regulation ("GDPR") adopted by the European Union and the California Privacy Rights Act ("CRPA") and the California Consumer Privacy Act, as amended by the CRPA (the "CCPA"), can expose us to investigations and enforcement actions by regulatory authorities and claims from individuals potentially resulting in penalties and significant legal liability, if our information technology security efforts are inadequate. In addition, we rely upon

technology suppliers, including cloud-based data management applications hosted by third-party service providers, whose security and information technology systems are subject to similar risks.

Significant disruption in either our or our service providers' or suppliers' information technology or the security of our products could impede 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 talent or are otherwise unsuccessful in the execution of our management succession plans.***

Our continued success depends, in large part, on our ability to hire and retain qualified people and execute on our talent management and succession plans, 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.

***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.

### **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 exposes us to certain financial, economic, political, and other risks, including those listed below.

***Domestic and Global Economic Conditions.*** We have been impacted and may continue to be negatively impacted by general domestic and global economic conditions, although we cannot predict the extent to which such conditions may negatively impact our business. These include, but are not limited to, conditions impacting inflation, credit and capital markets, interest rates, tax law, including tax rate and policy changes, factors



affecting global economic stability, and the political environment relating to health care. 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 United States, 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 “*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 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. The effective dates of implementation, the interactions of tax reforms in multiple jurisdictions, and uncertainty related to dispute resolution mechanisms could impact our provision for income taxes.
- ***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.*** In addition to the factors enumerated above, we are from time to time impacted by a variety of other factors associated with doing business internationally that can harm our future results, including 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;
- military conflict, political unrest, or wars; 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 in which we transact business, have the effect of increasing our reported revenues even when the volume of sales outside of the United States 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 outside of the United States), 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, we 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, including the European Union's European Commission who promulgated the European Medical Device Regulation ("EU MDR"). 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. More specifically relating to the EU MDR which came into effect in May 2017 and became applicable in May 2021 with a staggered transition period, all regulated products must be assessed by notified bodies (organizations designated by EU member states) as to whether they meet the technical requirements of the EU MDR before entering the market in Europe. During the transition period, with the influx of submissions to the notified bodies, any delay on obtaining approvals may result in a disruption of device supply or a further delay in getting a device to market. 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 EU MDR requires a revised MRA. If an MRA covering the EU 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 EU MDR requirements. If these measures are unable to be taken, it may no longer be possible to place such devices on the EU market.

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, the European Commission, 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.

We are also subject to various United States and foreign 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.

In addition, as a global company, we are subject to global data privacy and security laws, regulations and codes of conduct that apply to our businesses. We are required to comply with increasingly complex and changing legal and regulatory requirements that govern the collection, use, storage, security, transfer, disclosure and other processing of personal data in the United States and in other countries, which may include, but are not limited to, The Health Insurance Portability and Accountability Act, as amended (“HIPAA”), The Health Information Technology for Economic and Clinical Health Act, the CCPA, the CRPA, and the GDPR. The GDPR imposes stringent European Union data protection requirements and provides for significant penalties for noncompliance. HIPAA also imposes stringent data privacy and security requirements and the regulatory authority has imposed significant fines and penalties on organizations found to be out of compliance. The CCPA and the CRPA provides consumers with a private right of action against companies who have a security breach due to lack of appropriate security measures. We or our third-party providers and business partners may also be subjected to audits or investigations by one or more domestic or foreign government agencies relating to compliance with information security and privacy laws and regulations, and noncompliance with the laws and regulations could result in substantial and material fines or class action litigation.

Additional risks related to government regulation are also described under “*Health Care Legislation and Other Regulations*” in the risk factor above titled “*Because we operate globally, our business is subject to a variety of risks associated with international sales and operations.*”

***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.

***Climate change, or legal, regulatory or market measures to address climate change, may materially adversely affect our financial condition and business operations.***

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our future operations from natural disasters and extreme weather conditions, such as hurricanes, tornadoes, seismic events, wildfires, or flooding. Such extreme weather conditions could pose physical risks to our facilities and disrupt operation of our supply chain and may impact operational costs. Concern over climate change could result in new legal or regulatory requirements designed to mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory requirements, we may experience increased compliance burdens and costs to meet the regulatory obligations, and it may adversely affect our raw material sourcing, manufacturing operations, and the distribution of our products.

***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

### Asia

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

(1) Owned property.

(2) Leased property.

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, 2023, there were 8,019 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*

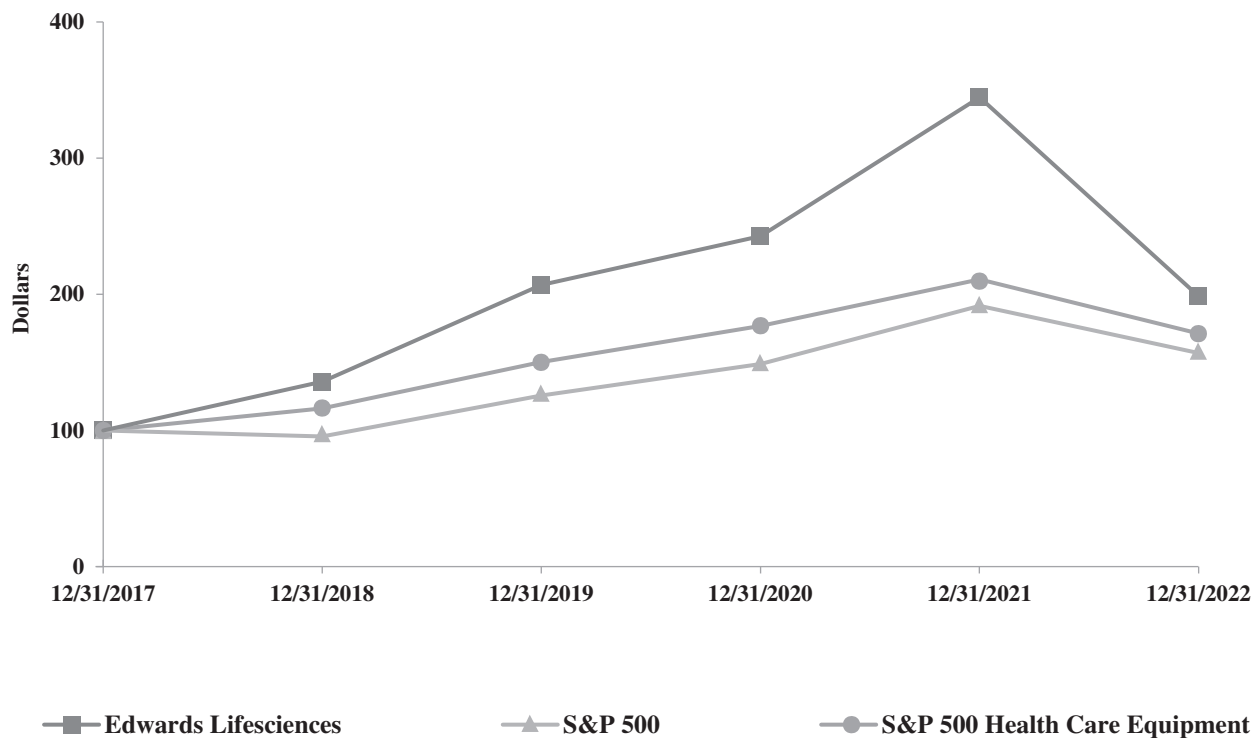
<u>Period</u>	<u>Total Number of Shares (or Units) Purchased (a)</u>	<u>Average Price Paid per Share (or Unit)</u>	<u>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions) (b)</u>
October 1, 2022 through October 31, 2022 . . . . .	1,381,903	\$83.66	1,381,903	\$1,666.0
November 1, 2022 through November 30, 2022 . .	8,284,153	72.91	8,283,860	1,061.6
December 1, 2022 through December 31, 2022 . .	2,003,416	72.91	2,003,416	915.6
Total . . . . .	<u>11,669,472</u>	74.18	<u>11,669,179</u>	

- (a) The difference between the total number of shares (or units) purchased and the total number of shares (or units) purchased as part of publicly announced plans or programs is due to shares withheld by us to satisfy tax withholding obligations in connection with the vesting of restricted stock units issued to employees.
- (b) On May 4, 2021, the Board of Directors approved a stock repurchase program providing for up to \$1.0 billion of repurchases of our common stock. In July 2022, the Board of Directors approved an additional \$1.5 billion of repurchases of our common stock under this program, effective July 28, 2022. Repurchases under the program may be made on the open market, including pursuant to a Rule 10b5-1 plan, and in privately negotiated transactions. The repurchase program does not have an expiration date.

*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, 2017 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				
	2018	2019	2020	2021	2022
Edwards Lifesciences	\$135.90	\$206.98	\$242.83	\$344.82	\$198.59
S&P 500	95.62	125.72	148.85	191.58	156.89
S&P 500 Health Care Equipment	116.24	150.32	176.83	211.05	171.25

**Item 6. [Reserved]**

**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, 2022. Also discussed is our financial position as of December 31, 2022. 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 2021 compared to 2020 and a discussion related to our consolidated cash flows for 2021 compared to 2020, refer to Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2021 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 14, 2022.

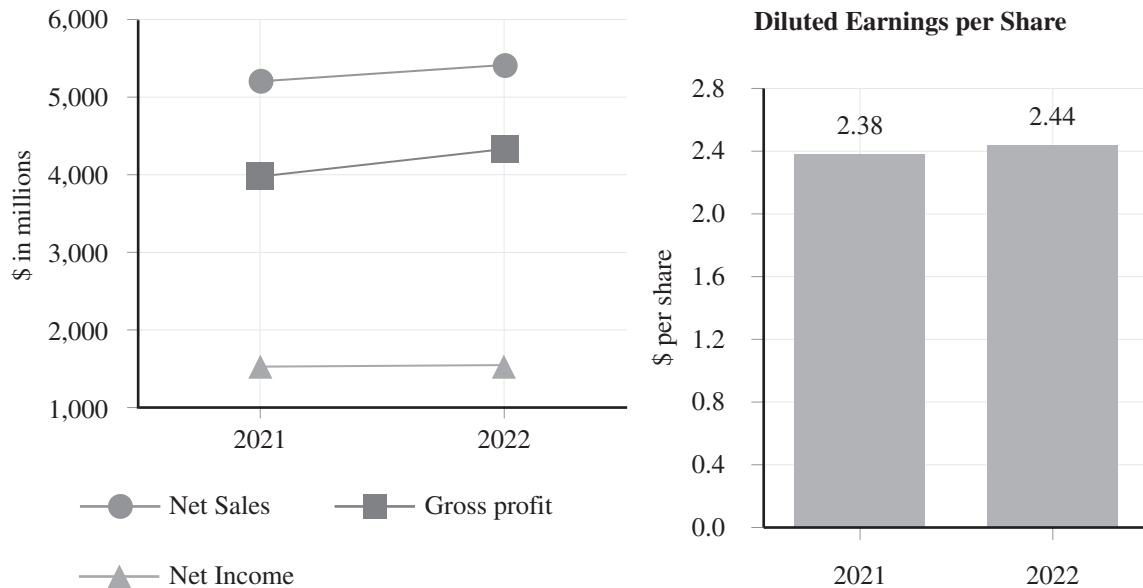
**Overview**

We are the global leader in patient-focused medical innovations for structural heart disease and critical care monitoring. Driven by a passion to help patients, we partner with the world’s leading clinicians and researchers



and invest in research and development to transform care for those impacted by structural heart disease or who require hemodynamic monitoring during surgery or in intensive care. We conduct operations worldwide and are managed in the following geographical regions: United States, Europe, Japan, and Rest of World. Our products are categorized into the following areas: Transcatheter Aortic Valve Replacement (“TAVR”), Transcatheter Mitral and Tricuspid Therapies (“TMTT”), Surgical Structural Heart (“Surgical”), and Critical Care.

### Financial Highlights and Market Update



### COVID-19 and Macroeconomic Uncertainties

The COVID-19 pandemic has adversely impacted, and may 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 maintain access for patients to our life-saving technologies while providing continuous front-line support to our clinician partners, and protecting the well-being of our employees. 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 to address potential supply constraints.

During the first quarter of 2021, COVID-19 stressed the global healthcare system during the winter months. However, we saw strong recovery beginning in the second quarter of 2021 as widespread vaccine adoption contributed to an increased number of patients. However, the Delta variant had a significant impact on hospital resources during the last two months of the third quarter of 2021, and the Omicron variant had a significant impact during December 2021, especially in the United States.

During the first quarter of 2022, the Omicron variant had a pronounced impact on hospital capacity, resources, and procedure volumes in January 2022, especially in the United States. Our 2022 sales were also impacted by slower than expected improvement in United States hospital staffing shortages and foreign currency headwinds. In the second half of 2022, we faced COVID-19 headwinds in Japan, which created significant strain on hospital capacity.

In addition to the impacts described above, the global economy, including the financial and credit markets, has recently experienced extreme volatility and disruptions, including increases to inflation rates, rising interest

rates, declines in consumer confidence, declines in economic growth, and uncertainty about economic stability. The severity and duration of the impact of these conditions on our business cannot be predicted. See Item 1A, “*Risk Factors*,” for additional information.

### 2022 Financial Highlights

Despite the challenges to our business in 2022 due to COVID-19 and macroeconomic factors, our net sales for 2022 were \$5.4 billion, representing an increase of \$149.9 million over 2021, driven by sales growth of our TAVR products.

Our gross profit increase in 2022 was driven by our sales growth and the positive impact of our foreign currency hedging program.

The increase in our diluted earnings per share in 2022 was driven by a) the aforementioned increase in our gross profit and b) a decrease in our diluted weighted-average shares outstanding, driven by our increased share repurchase activity. This increase was partially offset by a) changes in the fair value of our contingent consideration liabilities, which resulted in a \$121.6 million after tax gain in 2021 compared to a \$35.0 million after tax gain in 2022, b) an after-tax charge of \$47.0 million in 2022, primarily related to the impairment of intangible assets resulting from our decision to exit our *HARPOON* surgical mitral repair system program, and c) increased sales and marketing and research and development expenses in 2022.

### 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. Despite the challenges of the COVID-19 pandemic, our dedicated field teams have found creative ways to support physicians, our engineers continued to advance innovation, and our colleagues worked diligently to keep our clinical trials on track. In 2022, we invested 17.6% of our net sales in research and development. The following is a summary of important developments during 2022:

- we received United States Food and Drug Administration (“FDA”) approval for the *MITRIS RESILIA* valve, a tissue valve replacement specifically designed for the heart’s mitral position;
- we received CE Mark approval for the *PASCAL Precision* transcatheter valve repair system for patients suffering from mitral and tricuspid regurgitation, and FDA approval for *PASCAL Precision* for patients with degenerative mitral regurgitation; and
- we launched the *SAPIEN 3 Ultra RESILIA* valve following FDA approval.

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	
	2022	2021	\$	%
United States .....	\$3,132.6	\$2,963.1	\$169.5	5.7%
Europe .....	1,174.8	1,190.3	(15.5)	(1.3)%
Japan .....	473.6	528.9	(55.3)	(10.4)%
Rest of World .....	601.4	550.2	51.2	9.3%
Outside of the United States .....	2,249.8	2,269.4	(19.6)	(0.9)%
Total net sales .....	\$5,382.4	\$5,232.5	\$149.9	2.9%

Net sales outside of the United States 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.*”

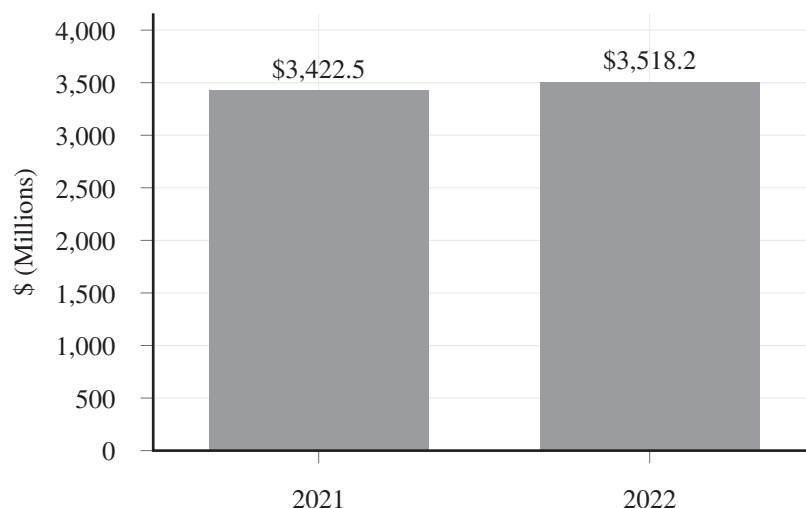
### Net Sales by Product Group

(dollars in millions)

	Years Ended December 31,		Change	
	2022	2021	\$	%
Transcatheter Aortic Valve Replacement .....	\$3,518.2	\$3,422.5	\$ 95.7	2.8%
Transcatheter Mitral and Tricuspid Therapies .....	116.1	86.0	30.1	35.1%
Surgical Heart Valve Therapy .....	893.1	889.1	4.0	0.4%
Critical Care .....	855.0	834.9	20.1	2.4%
Total net sales .....	\$5,382.4	\$5,232.5	\$149.9	2.9%

### *Transcatheter Aortic Valve Replacement*

For the years ended December 31, 2022 and 2021:



The increase in net sales of TAVR products was driven by:

- higher sales of the *Edwards SAPIEN* platform in 2022, primarily the *Edwards SAPIEN 3 Ultra* valve in the United States, Europe, and Rest of World, the *Edwards SAPIEN 3 Ultra RESILIA* valve in the United States, and the *Edwards SAPIEN 3* in Japan;

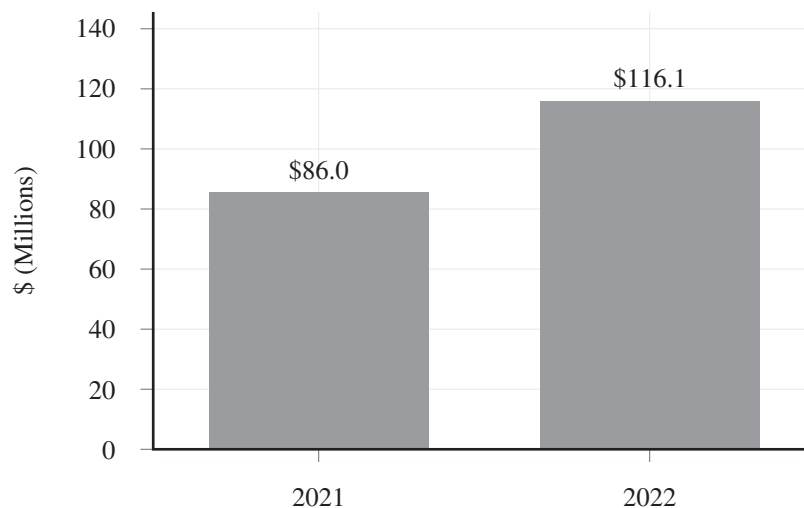
partially offset by:

- foreign currency exchange rate fluctuations, which decreased net sales outside of the United States by \$140.2 million primarily due to the weakening of the Euro and the Japanese yen against the United States dollar.

During 2022, we continued to advance our EARLY TAVR pivotal trial, studying the treatment of severe aortic stenosis patients before their symptoms develop, and our PROGRESS pivotal trial, studying moderate aortic stenosis patients. During the second quarter of 2022, we began treating patients in our ALLIANCE pivotal trial, studying our next-generation TAVR technology, *SAPIEN X4*, and during the fourth quarter of 2022, we began the introduction of the *SAPIEN 3 Ultra Resilia* valve in the United States.

### ***Transcatheter Mitral and Tricuspid Therapies***

For the years ended December 31, 2022 and 2021:



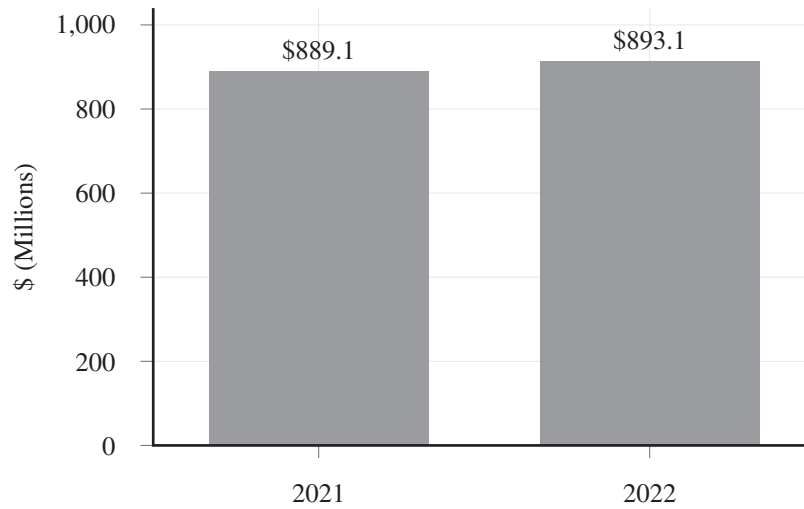
The increase in net sales of TMTT products was due primarily to continued adoption of our *PASCAL* system in Europe.

During August 2022, we received European regulatory approval for *PASCAL Precision* for patients suffering from mitral and tricuspid regurgitation, and in September 2022, we received FDA approval for *PASCAL Precision* for patients with degenerative mitral regurgitation. In mitral replacement, we continued to treat patients through the ENCIRCLE pivotal trial for *SAPIEN M3* and completed enrollment in the MISCEND early feasibility study for *EVOQUE Eos*. We also continued to make progress in enrolling the TRISCEND II pivotal trial of the *EVOQUE* replacement system and the CLASP IITR pivotal trial with the *PASCAL* repair system in patients with symptomatic, severe tricuspid regurgitation.



### ***Surgical Structural Heart***

For the years ended December 31, 2022 and 2021:

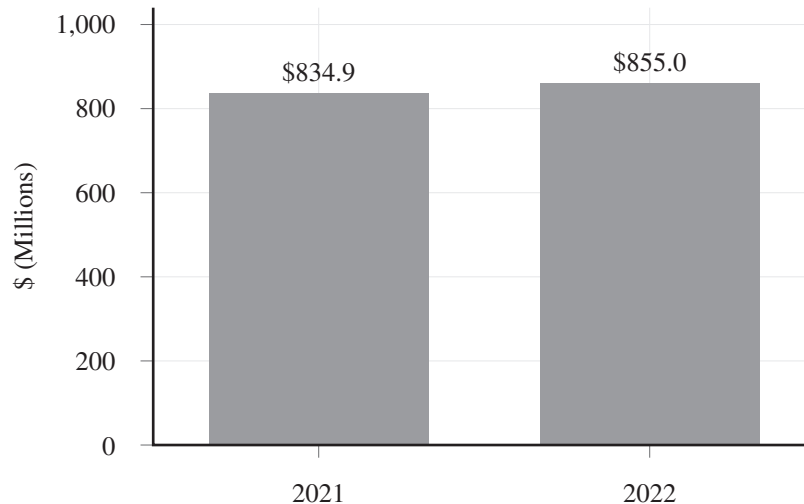


The increase in net sales of Surgical products was due primarily to strong adoption of the *INSPIRIS RESILIA* aortic valve, primarily in the United States and Europe, and the *MITRIS RESILIA* valve, primarily in the United States. These increases were partially offset by the impact of foreign currency exchange rate fluctuations, which decreased net sales outside of the United States by \$46.5 million primarily due to the weakening of the Euro and the Japanese yen against the United States dollar.

In March 2022, we received FDA approval for the *MITRIS RESILIA* valve and initiated the product launch in the United States in April 2022. *MITRIS RESILIA* is a tissue valve replacement specifically designed for the heart's mitral position and incorporates our advanced *RESILIA* technology. In early 2023, we began enrolling patients in our MOMENTS clinical study to demonstrate the durability of *RESILIA* tissue in the mitral position.

### ***Critical Care***

For the years ended December 31, 2022 and 2021:



The increase in net sales of Critical Care products was driven by:

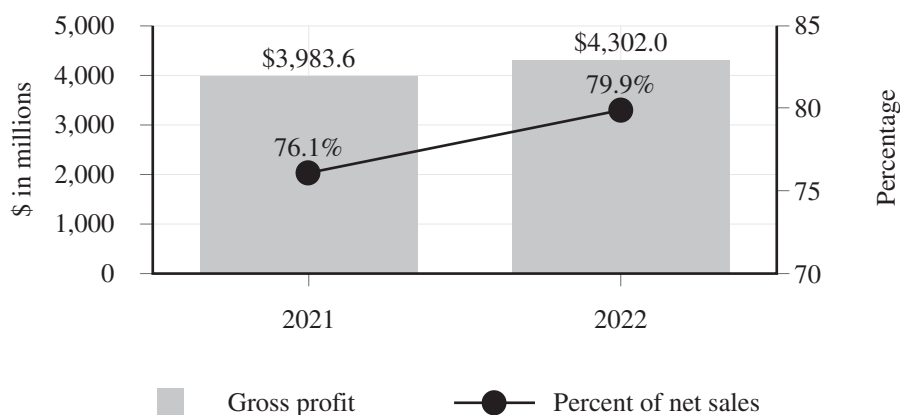
- increased demand for our capital products, primarily the *HemoSphere* monitoring platform in the United States and Japan;
- increased demand for our pressure monitoring products, primarily in the United States; and
- increased demand for our enhanced surgical recovery products, primarily in the United States;

partially offset by:

- foreign currency exchange rate fluctuations, which decreased net sales outside of the United States by \$39.5 million primarily due to the weakening of the Japanese yen and the Euro against the United States dollar.

### Gross Profit

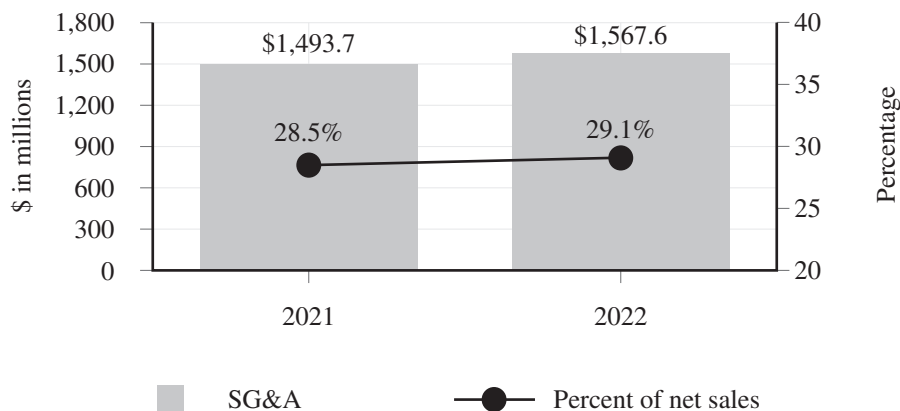
For the years ended December 31, 2022 and 2021:



The increase in gross profit as a percentage of net sales in 2022 compared to 2021 was driven primarily by a 3.6 percentage point increase from the impact of our foreign currency hedging program, which includes hedge contract gains and natural hedges (primarily the strengthening of the United States dollar against the Euro and the Japanese yen).

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

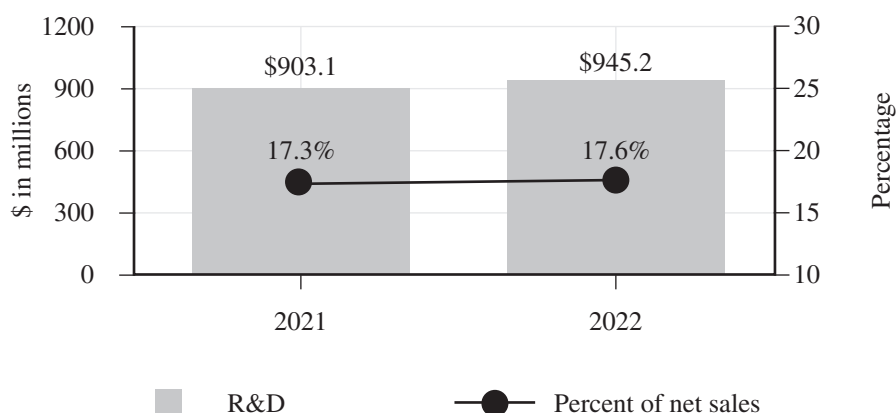
For the years ended December 31, 2022 and 2021:



SG&A expenses increased in 2022 compared to 2021 due primarily to a resumption of in-person commercial activities following COVID-19 and higher field-based personnel-related costs, primarily TAVR and TMTT in the United States. Foreign currency exchange rate fluctuations decreased expenses by \$63.1 million due primarily to the strengthening of the United States dollar against the Euro and the Japanese yen.

### Research and Development (“R&D”) Expenses

For the years ended December 31, 2022 and 2021:



R&D expenses increased marginally in 2022 compared to 2021 due primarily to continued investments in our transcatheter innovations, including increased clinical trial activity.

### Change in Fair Value of Contingent Consideration Liabilities, net

The change in fair value of contingent consideration liabilities resulted in income of \$35.8 million and \$124.1 million in 2022 and 2021, respectively. The income in 2022 was due to changes in projected probabilities of milestone achievement and our decision in the third quarter of 2022 to exit our *HARPOON* surgical mitral repair system program. The income in 2021 was attributable to changes in the projected probabilities of milestone achievements and the projected timing of cash inflows from product sales.

### Special Charge

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

### Interest Expense

Interest expense was \$19.2 million and \$18.4 million in 2022 and 2021, respectively. The increase in interest expense resulted primarily from lower capitalized interest due to decreased facilities construction.

### Interest Income

Interest income was \$35.5 million and \$17.4 million in 2022 and 2021, respectively. The increase in interest income resulted primarily from a higher average yield on our investments.

**Other Income, net**  
(in millions)

	<b>Years Ended December 31,</b>	
	<u>2022</u>	<u>2021</u>
Foreign exchange losses (gains), net . . . . .	\$ 1.2	\$ (5.0)
Gain on insurance settlement . . . . .	(3.8)	—
Loss (gain) on investments . . . . .	1.1	(5.8)
Non-service cost components of net periodic pension benefit cost . . . . .	(1.1)	0.3
Other . . . . .	<u>—</u>	<u>(2.2)</u>
Total other income, net . . . . .	<u>\$ (2.6)</u>	<u>\$ (12.7)</u>

The net foreign exchange losses (gains) relate to the foreign currency fluctuations primarily in our global trade and intercompany receivable and payable balances, partially offset by the gains and losses on foreign currency derivative instruments.

The gain on insurance settlement relates to an insurance recovery for damaged cargo shipments of heart valves.

The loss (gain) on investments primarily represents our net share of gains and losses in investments accounted for under the equity method, and realized gains and losses on investments in equity securities.

The non-service cost components of net periodic pension benefit cost includes the costs or gains 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**  
(\$ in millions)

	<b>Years Ended December 31,</b>		<b>Change</b>	
	<u>2022</u>	<u>2021</u>	<u>\$</u>	<u>%</u>
Provision for income taxes . . . . .	\$245.5	\$198.9	\$46.6	23.4%
Effective tax rate . . . . .	13.9%	11.7%		

Our effective income tax rate in 2022 and 2021 was 13.9% and 11.7%, respectively. Our effective tax rate for 2022 increased in comparison to 2021 primarily due to the decrease in the tax benefit from the change in fair value of contingent consideration liabilities and the decrease in the excess tax benefit from employee share-based compensation.

In 2022, the difference between our 13.9% effective tax rate and the Federal statutory rate of 21% was primarily due to (1) foreign earnings taxed at lower rates, (2) Federal and California research and development credits, (3) the excess tax benefit from employee share-based compensation and (4) the tax benefit from the change in fair value of contingent consideration liabilities.

As of December 31, 2022, we had \$189.8 million of gross 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 into the distant future.



As of December 31, 2022, our gross uncertain tax positions were \$475.3 million. We estimate that these liabilities would be reduced by \$182.1 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 \$293.2 million, if not required, would favorably affect our effective tax rate.

In the normal course of business, the Internal Revenue Service (“IRS”) and other taxing authorities are in different stages of examining various years of our tax filings. During these audits, we may receive proposed audit adjustments that could be material. Therefore, there is a possibility that an adverse outcome in these audits could have a material effect on our results of operations and financial condition. 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 eventual 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 for any adjustments that may result from our uncertain tax positions.

We executed an Advance Pricing Agreement (“APA”) in 2018 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 (collectively “Surgical/TAVR”) intercompany royalty transactions, then reverted to IRS examination for further consideration as part of the respective years’ regular tax audits. In addition, we executed other bilateral 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 all the APAs which cover transactions with Japan for the years 2020 and forward. An APA between Switzerland and Japan covering tax years 2020 through 2024 was executed in 2021. The execution of the other APA renewals depends on many variables outside of our control.

At December 31, 2022, 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 India for years from 2010 and on.

The audits of our United States federal income tax returns through 2014 have been closed. The IRS fieldwork for the 2015 through 2017 tax years was completed during the second quarter of 2021, except for transfer pricing and related matters. The IRS began its examination of the 2018 through 2020 tax years during the first quarter of 2022.

During 2021, we received a Notice of Proposed Adjustment (“NOPA”) from the IRS for the 2015-2017 tax years relating to transfer pricing involving certain Surgical/TAVR intercompany royalty transactions between our United States and Switzerland subsidiaries. The NOPA proposes an increase to our United States taxable income, which could result in additional tax expense for this period of approximately \$210 million and represents a significant change to previously agreed upon transfer pricing methodologies for these types of transactions. We have formally disagreed with the NOPA and submitted a formal protest on the matter during the fourth quarter of 2021. During the second quarter of 2022, we received the IRS’s rebuttal to our protest and were notified that the case had been transferred to the IRS Independent Office of Appeals. The opening conference is scheduled for the first quarter of 2023. We continue to evaluate all possible remedies available to us, which could take several years to resolve. We believe the amounts previously accrued related to this uncertain tax position are sufficient and, accordingly, have not accrued any additional amount based on the NOPA received. While no payment of any amount related to the NOPA is required to be made, if at all, until all applicable proceedings have been completed, we made an advance payment of tax in November 2022 to prevent the further accrual of interest on any potential deficiency.

Certain Surgical/TAVR intercompany royalty transactions covering tax years 2015 through 2022 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, 2022. We have considered this information, as well as information regarding the NOPA and rebuttal described above, in our evaluation of our uncertain tax positions. The impact of 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 in our existing uncertain tax positions may occur in the next 12 months and, therefore, have continued to record the uncertain tax positions as a long-term liability.

On August 16, 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law. The IRA includes, among other provisions, changes to the U.S. corporate income tax system, including (1) a 15% minimum tax based on “adjusted financial statement income,” which is effective for tax years beginning after December 31, 2022, and (2) a one percent excise tax on net repurchases of stock after December 31, 2022. While we continue to evaluate the IRA and its application to our business, we do not expect the IRA will have a material impact on our consolidated financial statements.

We have received tax incentives in certain non-United States tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were \$247.4 million (\$0.40 per diluted share) and \$208.0 million (\$0.33 per diluted share) for the years ended December 31, 2022 and 2021, respectively.

### **Liquidity and Capital Resources**

Our sources of cash liquidity include cash and cash equivalents, short-term investments, cash from operations, and amounts available under credit facilities. We believe that these sources are sufficient to fund the current and long-term requirements of working capital, capital expenditures, and other financial commitments. 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”) 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 three remaining annual installments, as outlined in the contractual obligations table presented under “Material Cash Requirements” below. As of December 31, 2022, we had a remaining tax obligation of \$188.5 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, 2022, cash and cash equivalents and short-term investments held in the United States and outside of the United States were \$731.8 million and \$483.5 million, respectively. During 2022, we repatriated cash of \$934.0 million. We assert that \$1.0 billion of our foreign earnings continue to be permanently reinvested and our intent is to repatriate \$580.8 million of our foreign earnings as of December 31, 2022. The estimated net tax liability on the indefinitely reinvested earnings if repatriated is \$14.9 million.

We had a Five-Year Credit Agreement (the “Prior Credit Agreement”) which was scheduled to mature on April 28, 2023 and provided up to an aggregate of \$750.0 million in borrowings in multiple currencies. In July 2022, we entered into a new Five-Year Credit Agreement (the “New Credit Agreement”) which provides for a \$750.0 million multi-currency unsecured revolving credit facility and replaced the Prior Credit Agreement. The New Credit Agreement matures on July 15, 2027. We may increase the amount available under the New Credit Agreement by up to an additional \$250.0 million in the aggregate and extend the maturity date for an additional year, subject to agreement of the lenders. The New Credit Agreement contains various financial and other covenants, including a maximum leverage ratio, as defined in the agreement. As of December 31, 2022, no amounts were outstanding, and we were in compliance with all covenants under the New Credit Agreement.

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, 2022, we have not elected to redeem any of the 2018 Notes. As of December 31, 2022, the carrying value of the 2018 Notes was \$596.3 million. For further information on our debt, see Note 10 to the “*Consolidated Financial Statements.*”

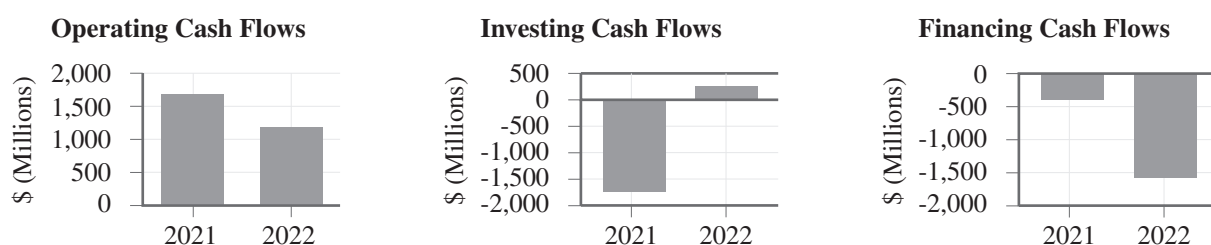
From time to time, we repurchase shares of our common stock under share repurchase programs authorized by the Board of Directors. We consider several factors in determining when to execute share repurchases, including, among other things, expected dilution from stock plans, cash capacity, and the market price of our common stock. During 2022, under the Board authorized repurchase program, we repurchased a total of 20.0 million shares at an aggregate cost of \$1.7 billion. As of December 31, 2022, we had remaining authority to purchase \$915.6 million of our common stock under the share repurchase program.

Certain of our business acquisitions involve contingent consideration arrangements. Payment of additional consideration in the future may be required, contingent upon the acquired business reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. For further information, see Note 11 to the “*Consolidated Financial Statements.*”

We have purchased options to acquire and have agreed to provide promissory notes to various entities. These arrangements could result in additional cash outlays in the future should we decide to exercise the options or should the entities draw on the promissory notes. For further information, see Note 8 to the “*Consolidated Financial Statements.*”

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 \$70 million. We made a one-time \$100.0 million payment to Abbott in July 2020, and are making quarterly payments in subsequent years. For further information, see Note 3 to the “*Consolidated Financial Statements.*”

**Consolidated Cash Flows—For the twelve months ended December 31, 2022 and 2021**



Net cash flows provided by **operating activities** of \$1.2 billion for 2022 decreased \$513.9 million from 2021 due to an increase in tax payments, an increase in inventory builds compared to the prior year, and a higher bonus payout in 2022 associated with 2021 performance.

Net cash provided by **investing activities** of \$252.3 million in 2022 consisted primarily of net proceeds from investments of \$661.0 million, partially offset by capital expenditures of \$244.6 million and payments of \$109.6 million for options to acquire other companies. For further information, see Note 8 to the “*Consolidated Financial Statements.*”

Net cash used in investing activities of \$1.7 billion in 2021 consisted primarily of net purchases of investments of \$1.4 billion and capital expenditures of \$325.8 million.

We currently anticipate making capital expenditures of approximately \$300.0 million in 2023 as we continue to invest in our operations.

Net cash used in **financing activities** of \$1.6 billion in 2022 consisted primarily of purchases of treasury stock of \$1.7 billion, partially offset by proceeds from stock plans of \$146.4 million.

Net cash used in financing activities of \$356.3 million in 2021 consisted primarily of purchases of treasury stock of \$512.8 million, partially offset by proceeds from stock plans of \$158.6 million.

### **Material Cash Requirements**

A summary of our material cash requirements as of December 31, 2022 is as follows (in millions):

	Payments Due by Period				
	Total	Year 1	Years 2-3	Years 4-5	After 5 Years
<b>Contractual Obligations</b>					
Debt	\$ 600.0	\$ —	\$ —	\$ —	\$600.0
Operating leases	102.7	27.0	31.0	18.7	26.0
Interest on debt	106.4	19.6	39.3	38.9	8.6
Transition tax on unremitted foreign earnings and profits (a)	188.5	47.1	141.4	—	—
Litigation settlement obligation (minimum payments)	162.5	50.0	100.0	12.5	—
Pension obligations (b)	2.4	2.4	—	—	—
Purchase and other commitments (c)	34.3	18.5	12.0	2.8	1.0
Total contractual cash obligations (d), (e)	<u>\$1,196.8</u>	<u>\$164.6</u>	<u>\$323.7</u>	<u>\$72.9</u>	<u>\$635.6</u>

- (a) As of December 31, 2022, we had recorded \$188.5 million of income tax liabilities related to the one-time transition tax that resulted from the enactment of the 2017 Act. The transition tax is due in eight annual installments, with the first five installments paid in 2018 through 2022. The remaining installment amounts will be equal to 15% of the total liability payable in 2023, 20% in 2024, and 25% in 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, 2022 was \$23.5 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, 2022, the gross liability for uncertain tax positions, including interest, was \$519.8 million and relates primarily to transfer pricing matters which are discussed in detail in Note 17 to the “*Consolidated Financial Statements*.” Based upon the information currently available and numerous possible outcomes, we cannot reasonably estimate 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 judgments and estimates. These matters that are subject to judgments and estimates 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.

### ***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; and
- projected payment dates.

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 United States 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, 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. 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 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. If a reasonable estimate of a known or probable loss cannot be made, but a range of probable losses can be estimated, the low-end of the range of losses is recognized if no amount within the range is a better estimate than any other. If we determine that a loss is possible, but not probable, and the range of the loss can be reasonably determined, then we disclose the range of the possible loss. 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, United States 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, 2022, we had \$1.6 billion of investments in debt securities which had an average remaining term to maturity of 0.98 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, 2022 would have resulted in a \$7.8 million to \$15.5 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, 2022, we had \$600.0 million of 2018 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 Secured Overnight Financing Rate (“SOFR”). As of December 31, 2022, there were no borrowings outstanding under the Credit Agreement. Based on our December 31, 2022 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, 2022, a hypothetical 1.0% absolute increase in market interest rates would decrease the fair value of the fixed-rate debt by approximately \$26.7 million. This hypothetical change in interest rates would not impact the interest expense on the fixed-rate debt.

For more information related to outstanding debt obligations, see Note 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, 2022 was \$2.0 billion. A hypothetical 10% increase (or decrease) in the value of the United States dollar against all hedged currencies would increase (or decrease) the fair value of these derivative contracts by \$158.2 million. Any gains or losses on the fair value of derivative contracts would generally be offset by gains and losses on the underlying transactions, so the net impact would not be significant to our financial condition or results of operations.

For more information related to outstanding foreign exchange contracts, see Note 2 and Note 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, 2022, 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 2022, 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, 2022, we had \$1.6 billion of investments in debt securities of various companies, of which \$1.1 billion were long-term. In addition, we had \$108.3 million of investments in equity instruments. Should these companies experience a decline in financial performance, financial condition or credit capacity, or fail to meet certain development milestones, 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, 2022**

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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, 2022 and 2021, 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, 2022, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 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, 2022, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the COSO.

### ***Basis for Opinions***

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

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

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

### ***Definition and Limitations of Internal Control over Financial Reporting***

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in

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

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

### ***Critical Audit Matter***

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

### ***Uncertain Tax Positions Related to Intercompany Transfer Pricing***

As described in Note 17 to the consolidated financial statements, the Company had an uncertain gross tax position liability balance of \$475.3 million as of December 31, 2022, of which a majority is related to intercompany transfer pricing. As disclosed by management, the Company is subject to income taxes in the United States and numerous foreign jurisdictions. 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 estimating the ultimate resolution to intercompany pricing controversies between countries when there are numerous possible outcomes. 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. In addition, 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 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 related to intercompany transfer pricing, including US federal filing positions, and the related final income 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 management's

assessment of possible outcomes of uncertain tax positions related to intercompany transfer pricing controversies between countries; 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 accurate 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 tax benefit to be realized, and the application of relevant tax laws.

/s/ PricewaterhouseCoopers LLP  
Irvine, California  
February 13, 2023

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



**EDWARDS LIFESCIENCES CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

(in millions, except par value)

	December 31,	
	2022	2021
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 769.0	\$ 862.8
Short-term investments (Note 7)	446.3	604.0
Accounts receivable, net of allowances of \$7.9 and \$9.3, respectively	643.0	582.2
Other receivables	56.1	82.7
Inventories (Note 5)	875.5	726.7
Prepaid expenses	110.0	85.2
Other current assets	195.9	237.1
Total current assets	3,095.8	3,180.7
Long-term investments (Note 7)	1,239.0	1,834.2
Property, plant, and equipment, net (Note 5)	1,632.8	1,546.6
Operating lease right-of-use assets (Note 6)	92.3	92.1
Goodwill (Note 9)	1,164.3	1,167.9
Other intangible assets, net (Note 9)	285.2	323.6
Deferred income taxes	484.0	246.7
Other assets	299.1	110.8
Total assets	\$ 8,292.5	\$ 8,502.6
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 201.9	\$ 204.5
Accrued and other liabilities (Note 5)	795.0	802.3
Operating lease liabilities (Note 6)	25.5	25.5
Total current liabilities	1,022.4	1,032.3
Long-term debt (Note 10)	596.3	595.7
Contingent consideration liabilities (Notes 8 and 11)	26.2	62.0
Taxes payable (Note 17)	143.4	190.0
Operating lease liabilities (Note 6)	69.5	69.1
Uncertain tax positions (Note 17)	267.5	259.0
Litigation settlement accrual (Note 3)	143.0	191.3
Other liabilities	217.5	267.3
Total liabilities	2,485.8	2,666.7
Commitments and contingencies (Notes 6, 10, and 18)		
<b>Stockholders' equity (Note 14)</b>		
Preferred stock, \$0.01 par value, authorized 50.0 shares, no shares outstanding	—	—
Common stock, \$1.00 par value, 1,050.0 shares authorized, 646.3 and 642.0 shares issued, and 608.3 and 624.1 shares outstanding, respectively	646.3	642.0
Additional paid-in capital	1,969.3	1,700.4
Retained earnings	7,590.0	6,068.1
Accumulated other comprehensive loss (Note 15)	(254.9)	(157.7)
Treasury stock, at cost, 38.0 and 17.9 shares, respectively	(4,144.0)	(2,416.9)
Total stockholders' equity	5,806.7	5,835.9
Total liabilities and stockholders' equity	\$ 8,292.5	\$ 8,502.6

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,		
	2022	2021	2020
Net sales	\$5,382.4	\$5,232.5	\$4,386.3
Cost of sales	1,080.4	1,248.9	1,080.6
Gross profit	4,302.0	3,983.6	3,305.7
Selling, general, and administrative expenses	1,567.6	1,493.7	1,228.4
Research and development expenses	945.2	903.1	760.7
Intellectual property litigation expenses, net (Note 3)	15.8	20.6	405.4
Change in fair value of contingent consideration liabilities, net (Note 11)	(35.8)	(124.1)	13.6
Special charge (Note 4)	60.7	—	—
Operating income	1,748.5	1,690.3	897.6
Interest expense	19.2	18.4	15.8
Interest income	(35.5)	(17.4)	(23.4)
Other income, net (Note 16)	(2.6)	(12.7)	(11.5)
Income before provision for income taxes	1,767.4	1,702.0	916.7
Provision for income taxes (Note 17)	245.5	198.9	93.3
Net income	<u>\$1,521.9</u>	<u>\$1,503.1</u>	<u>\$ 823.4</u>
<b>Share information</b> (Note 2):			
Earnings per share:			
Basic	\$ 2.46	\$ 2.41	\$ 1.32
Diluted	\$ 2.44	\$ 2.38	\$ 1.30
Weighted-average number of common shares outstanding:			
Basic	619.0	623.3	622.6
Diluted	624.2	631.2	631.9

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,		
	2022	2021	2020
Net income .....	\$1,521.9	\$1,503.1	\$823.4
Other comprehensive (loss) income, net of tax (Note 15):			
Foreign currency translation adjustments .....	(46.3)	(50.1)	32.4
Unrealized (loss) gain on hedges .....	(5.9)	57.4	(40.2)
Unrealized pension credits (costs) .....	13.7	11.6	(4.2)
Unrealized (loss) gain on available-for-sale investments .....	(77.5)	(24.1)	6.6
Reclassification of net realized investment loss to earnings .....	18.8	8.6	0.3
Other comprehensive (loss) income, net of tax .....	(97.2)	3.4	(5.1)
Comprehensive income .....	\$1,424.7	\$1,506.5	\$818.3

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,		
	2022	2021	2020
<b>Cash flows from operating activities</b>			
Net income	\$ 1,521.9	\$ 1,503.1	\$ 823.4
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	139.6	134.8	107.2
Non-cash operating lease cost	27.2	28.5	28.2
Stock-based compensation (Notes 2 and 14)	126.8	109.3	92.6
Impairment charges (Note 4)	55.1	4.0	—
Change in fair value of contingent consideration liabilities, net (Note 11)	(35.8)	(124.1)	13.6
Loss (gain) on investments, net	51.5	(36.8)	(21.2)
Deferred income taxes	(254.5)	(41.4)	(49.4)
Other	7.8	9.4	17.7
Changes in operating assets and liabilities:			
Accounts and other receivables, net	(84.1)	(91.1)	41.9
Inventories	(213.4)	19.0	(120.6)
Prepaid expenses and other current assets	0.1	7.9	(28.5)
Accounts payable and accrued liabilities	(21.4)	195.2	(84.5)
Litigation settlement accrual	(45.0)	(29.2)	270.5
Income taxes	(5.6)	62.0	(52.9)
Other	(52.0)	(18.5)	16.3
Net cash provided by operating activities	<u>1,218.2</u>	<u>1,732.1</u>	<u>1,054.3</u>
<b>Cash flows from investing activities</b>			
Capital expenditures	(244.6)	(325.8)	(407.0)
Purchases of held-to-maturity investments (Note 7)	(353.5)	(250.0)	(162.0)
Proceeds from sales and maturities of held-to-maturity investments (Note 7)	419.5	138.0	212.2
Purchases of available-for-sale investments (Note 7)	(315.8)	(1,629.3)	(689.7)
Proceeds from sales and maturities of available-for-sale investments (Note 7)	939.6	391.2	564.8
Payment for acquisition option (Note 8)	(109.6)	(13.1)	(10.0)
Issuances of notes receivable	(52.3)	(5.1)	(27.0)
Collections of notes receivable	18.0	20.0	—
Investments in intangible assets	(20.2)	(4.0)	(0.3)
Other	(28.8)	(44.4)	(12.1)
Net cash provided by (used in) investing activities	<u>252.3</u>	<u>(1,722.5)</u>	<u>(531.1)</u>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of debt	—	5.2	16.2
Payments on debt and finance lease obligations	(0.2)	(7.0)	(17.0)
Purchases of treasury stock	(1,727.1)	(512.8)	(625.4)
Proceeds from stock plans	146.4	158.6	140.5
Other	(3.6)	(0.3)	(1.2)
Net cash used in financing activities	<u>(1,584.5)</u>	<u>(356.3)</u>	<u>(486.9)</u>
Effect of currency exchange rate changes on cash, cash equivalents, and restricted cash	19.2	13.9	(20.5)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(94.8)	(332.8)	15.8
Cash, cash equivalents, and restricted cash at beginning of year	867.4	1,200.2	1,184.4
Cash, cash equivalents, and restricted cash at end of year	<u>\$ 772.6</u>	<u>\$ 867.4</u>	<u>\$1,200.2</u>

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

**EDWARDS LIFESCIENCES CORPORATION**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(in millions)

	<u>Common Stock</u>		<u>Treasury Stock</u>		<u>Additional Paid-in Capital</u>	<u>Retained Earnings</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Par Value</u>	<u>Shares</u>	<u>Amount</u>				
<b>BALANCE AT DECEMBER 31,</b>								
<b>2019</b> .....	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)			—
<b>BALANCE AT DECEMBER 31,</b>								
<b>2020</b> .....	636.4	636.4	12.1	(1,904.1)	1,438.1	4,565.0	(161.1)	4,574.3
Net income .....						1,503.1		1,503.1
Other comprehensive income, net of tax .....							3.4	3.4
Common stock issued under equity plans .....	5.6	5.6			153.0			158.6
Stock-based compensation expense .....					109.3			109.3
Purchases of treasury stock .....			5.8	(512.8)				(512.8)
<b>BALANCE AT DECEMBER 31,</b>								
<b>2021</b> .....	642.0	642.0	17.9	(2,416.9)	1,700.4	6,068.1	(157.7)	5,835.9
Net income .....						1,521.9		1,521.9
Other comprehensive loss, net of tax .....							(97.2)	(97.2)
Common stock issued under equity plans .....	4.3	4.3			142.1			146.4
Stock-based compensation expense .....					126.8			126.8
Purchases of treasury stock .....			20.1	(1,727.1)				(1,727.1)
<b>BALANCE AT DECEMBER 31,</b>								
<b>2022</b> .....	<u>646.3</u>	<u>\$646.3</u>	<u>38.0</u>	<u>\$(4,144.0)</u>	<u>\$1,969.3</u>	<u>\$7,590.0</u>	<u>\$(254.9)</u>	<u>\$ 5,806.7</u>

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 material VIEs; however, future events may require VIEs to be consolidated if the Company becomes the primary beneficiary.

**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.

**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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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.

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 a reduction to 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, 2022 and 2021, \$10.6 million and \$10.2 million, respectively, of deferred revenue associated with outstanding service contracts was recorded in "*Accrued and Other Liabilities*" and "*Other Liabilities*." During 2022, the Company recognized as revenue \$7.2 million that was included in the balance of deferred revenue as of December 31, 2021, and during 2021, the Company recognized as revenue \$7.3 million that was included in the balance of deferred revenue as of December 31, 2020.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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, 2022, 2021, and 2020, shipping costs of \$87.4 million, \$85.3 million, and \$74.0 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 at the time of purchase 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, United States government and agency securities, asset-backed securities, corporate debt securities, and municipal debt 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 3% 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.*"

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 length of time and the extent to which the security's fair value has been below 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.

**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 inception 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 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 and human resources personnel, and information technology. During the years ended December 31, 2022, 2021, and 2020, the Company allocated \$88.1 million, \$77.9 million, and \$63.1 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2022 and 2021 were \$43.7 million and \$33.7 million, respectively.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

At December 31, 2022 and 2021, \$128.6 million and \$125.8 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 \$133.9 million, \$127.0 million, and \$101.8 million for the years ended December 31, 2022, 2021, and 2020, respectively.

**Leases**

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 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.

**Acquisitions**

Businesses that the Company acquires are included in its results of operations as of the acquisition date. The purchase price is allocated to the assets acquired and liabilities assumed based on their estimated fair values. The excess of the purchase price over the fair values of identifiable assets and liabilities is recorded as goodwill. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred. Contingent consideration obligations incurred in connection with a business combination are recorded at their fair values on the acquisition date and remeasured on a quarterly basis, with changes in their fair value



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

recorded as an adjustment to earnings, until the related contingencies have been resolved. When the assets acquired do not meet the definition of a business combination, the transactions is accounted for as an asset acquisition. In an asset acquisition, the cost of the acquisition is allocated to the assets acquired and liabilities assumed based on their relative fair values. Upfront payments related to in-process research and development projects with no alternative future use are expensed upon acquisition.

**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 2022, 2021, and 2020, the Company did not record any goodwill 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 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 2022, the Company recorded a \$52.7 million impairment of certain developed technology and in-process research and development assets. For further information, see Note 4. In 2021 and 2020, the Company did not record any impairment loss related to its in-process research and development assets.

**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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 United States 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 the 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>2022</u>	<u>2021</u>	<u>2020</u>
Basic:			
Net income . . . . .	<u>\$1,521.9</u>	<u>\$1,503.1</u>	<u>\$823.4</u>
Weighted-average shares outstanding . . . . .	<u>619.0</u>	<u>623.3</u>	<u>622.6</u>
Basic earnings per share . . . . .	<u>\$ 2.46</u>	<u>\$ 2.41</u>	<u>\$ 1.32</u>
Diluted:			
Net income . . . . .	<u>\$1,521.9</u>	<u>\$1,503.1</u>	<u>\$823.4</u>
Weighted-average shares outstanding . . . . .	619.0	623.3	622.6
Dilutive effect of stock plans . . . . .	<u>5.2</u>	<u>7.9</u>	<u>9.3</u>
Dilutive weighted-average shares outstanding . . . . .	<u>624.2</u>	<u>631.2</u>	<u>631.9</u>
Diluted earnings per share . . . . .	<u>\$ 2.44</u>	<u>\$ 2.38</u>	<u>\$ 1.30</u>

Outstanding stock options, unvested restricted stock units, and unvested market-based restricted stock units to purchase approximately 3.6 million, 1.8 million, and 2.0 million shares for the years ended December 31, 2022, 2021, and 2020, respectively, 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 and market-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 each award's requisite service period (vesting period) on a straight-line basis. 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.

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

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Cost of sales . . . . .	\$ 22.8	\$ 20.4	\$ 17.2
Selling, general, and administrative expenses . . . . .	75.3	65.6	56.6
Research and development expenses . . . . .	<u>28.7</u>	<u>23.3</u>	<u>18.8</u>
Total stock-based compensation expense . . . . .	126.8	109.3	92.6
Income tax benefit . . . . .	<u>(21.6)</u>	<u>(18.9)</u>	<u>(15.4)</u>
Total stock-based compensation expense, net of tax . . . .	<u>\$105.2</u>	<u>\$ 90.4</u>	<u>\$ 77.2</u>

Upon a participant's retirement, all unvested stock options 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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 its currency exchange rate risk and its interest rate risk. 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 and cross currency swap contracts 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 the revaluation of 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 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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Recently Adopted Accounting Standards**

In November 2021, the Financial Accounting Standards Board (“FASB”) issued an amendment to the accounting guidance on government assistance. The guidance requires certain disclosures about transactions with a government that are accounted for by applying a grant or contribution model. The guidance was effective for annual periods beginning after December 15, 2021. The adoption of this guidance was applied prospectively and did not have an 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 \$15.8 million, \$20.6 million and \$405.4 million during 2022, 2021 and 2020, respectively.

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. 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 \$70 million. The Company made a one-time \$100.0 million payment to Abbott in July 2020, and is making quarterly payments in subsequent years. As of December 31, 2022, \$53.3 million was accrued in “*Accrued and other liabilities*” and \$143.0 million was accrued in “*Litigation settlement accrual*” on the consolidated balance sheet.

**4. SPECIAL CHARGE**

In September 2022, the Company decided to exit its *HARPOON* surgical mitral repair system program. As a result, the Company recorded a charge to its United States segment of \$62.3 million, of which \$60.7 million was included in “*Special Charge*” and \$1.6 million was included in “*Cost of Sales*” on the consolidated statements of operations. The charge primarily related to the full impairment of intangible assets associated with the technology for \$52.7 million (see Note 8 and Note 9) and other related exit costs. The Company believes that no additional contingent consideration is due and, in September 2022, recorded an \$11.7 million contingent consideration gain associated with the exit (see Note 11).



**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>2022</u>	<u>2021</u>
	(in millions)	
<b>Inventories</b>		
Raw materials . . . . .	\$ 156.4	\$ 132.8
Work in process . . . . .	177.4	164.3
Finished products . . . . .	541.7	429.6
	<u>\$ 875.5</u>	<u>\$ 726.7</u>
<b>Property, plant, and equipment, net</b>		
Land . . . . .	\$ 116.3	\$ 116.5
Buildings and leasehold improvements . . . . .	1,189.2	1,010.1
Machinery and equipment . . . . .	697.6	613.4
Equipment with customers . . . . .	37.4	39.2
Software . . . . .	87.5	88.2
Construction in progress . . . . .	255.2	333.8
	2,383.2	2,201.2
Accumulated depreciation . . . . .	(750.4)	(654.6)
	<u>\$1,632.8</u>	<u>\$1,546.6</u>
<b>Accrued and other liabilities</b>		
Employee compensation and withholdings . . . . .	\$ 268.7	\$ 319.7
Accrued rebates . . . . .	116.1	77.0
Property, payroll, and other taxes . . . . .	45.6	68.9
Research and development accruals . . . . .	66.9	58.2
Legal and insurance (Notes 3 and 18) . . . . .	81.4	79.1
Taxes payable . . . . .	50.6	30.6
Fair value of derivatives . . . . .	20.7	3.9
Accrued marketing expenses . . . . .	17.0	20.1
Accrued professional services . . . . .	6.6	11.9
Accrued realignment reserves . . . . .	15.6	19.1
Accrued relocation costs . . . . .	25.2	26.2
Other accrued liabilities . . . . .	80.6	87.6
	<u>\$ 795.0</u>	<u>\$ 802.3</u>

**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>2022</u>	<u>2021</u>	<u>2020</u>
Cash paid during the year for:			
Interest .....	\$ 19.3	\$ 20.2	\$ 19.9
Income taxes .....	\$504.1	\$182.5	\$197.9
Amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases .....	\$ 28.1	\$ 31.9	\$ 29.7
Non-cash investing and financing transactions:			
Right-of-use assets obtained in exchange for new lease liabilities .....	\$ 31.9	\$ 28.7	\$ 39.7
Capital expenditures accruals .....	\$ 42.6	\$ 54.3	\$ 80.4
Conversion of notes receivable to equity investment .....	\$ —	\$ 21.5	\$ 4.5

*Cash, Cash Equivalents, and Restricted Cash*

(in millions)

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Cash and cash equivalents .....	\$769.0	\$862.8	\$1,183.2
Restricted cash included in other current assets .....	0.5	1.5	16.6
Restricted cash included in other assets .....	3.1	3.1	0.4
Total cash, cash equivalents, and restricted cash .....	<u>\$772.6</u>	<u>\$867.4</u>	<u>\$1,200.2</u>

Amounts included in restricted cash primarily represent funds placed in escrow related to litigation and real estate purchases. Restricted cash as of December 31, 2020 also included 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 18 years, some of which include options to extend or terminate the leases.

Operating lease costs for the years ended December 31, 2022, 2021, and 2020 were \$28.8 million, \$29.7 million, and \$30.5 million, respectively. Short-term and variable lease costs were not material for the years ended December 31, 2022, 2021, and 2020.

**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):

	<b>As of December 31,</b>	
	<u>2022</u>	<u>2021</u>
Operating lease right-of-use assets . . . . .	<u>\$92.3</u>	<u>\$92.1</u>
Operating lease liabilities, current portion . . . . .	\$25.5	\$25.5
Operating lease liabilities, long-term portion . . . . .	<u>69.5</u>	<u>69.1</u>
Total operating lease liabilities . . . . .	<u>\$95.0</u>	<u>\$94.6</u>

Maturities of operating lease liabilities at December 31, 2022 were as follows (in millions):

2023 . . . . .	\$ 27.0
2024 . . . . .	18.5
2025 . . . . .	12.5
2026 . . . . .	10.5
2027 . . . . .	8.2
Thereafter . . . . .	<u>26.0</u>
Total lease payments . . . . .	102.7
Less: imputed interest . . . . .	<u>(7.7)</u>
Total lease liabilities . . . . .	<u>\$ 95.0</u>

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

	<b>Years Ended December 31,</b>	
	<u>2022</u>	<u>2021</u>
Weighted-average remaining lease term (in years) . . . . .	6.4	6.2
Weighted-average discount rate . . . . .	1.8%	2.5%

As of December 31, 2022, the Company had additional operating lease commitments of \$14.1 million for office spaces 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, 2022				December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b><u>Held-to-maturity</u></b>								
Bank time deposits . . . . .	\$ 96.0	\$—	\$ —	\$ 96.0	\$ 162.0	\$—	\$ —	\$ 162.0
<b><u>Available-for-sale</u></b>								
Bank time deposits . . . . .	\$ —	\$—	\$ —	\$ —	\$ 2.5	\$—	\$ —	\$ 2.5
Commercial paper . . . . .	—	—	—	—	127.7	—	—	127.7
United States government and agency securities . . . . .	137.7	—	(6.1)	131.6	147.4	0.6	(0.7)	147.3
Asset-backed securities . . . . .	380.6	—	(14.0)	366.6	515.2	0.3	(2.9)	512.6
Corporate debt securities . . . . .	1,028.1	—	(47.8)	980.3	1,397.1	2.0	(8.3)	1,390.8
Municipal securities . . . . .	2.7	—	(0.2)	2.5	2.8	—	—	2.8
	\$1,549.1	\$—	\$(68.1)	\$1,481.0	\$2,192.7	\$ 2.9	\$(11.9)	\$2,183.7

The cost and fair value of investments in debt securities, by contractual maturity, as of December 31, 2022 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 . . . . .	\$91.5	\$91.5	\$ 362.0	\$ 354.8
Due after 1 year through 5 years . . . . .	4.5	4.5	753.8	710.8
Due after 5 years through 10 years . . . . .	—	—	6.0	5.7
Instruments not due at a single maturity date (a) . . . . .	—	—	427.3	409.7
	\$96.0	\$96.0	\$1,549.1	\$1,481.0

(a) Consists of mortgage- and asset-backed securities.

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)**

The following tables present gross unrealized losses and fair values for those investments that were in an unrealized loss position as of December 31, 2022 and 2021, aggregated by investment category and the length of time that individual securities have been in a continuous loss position (in millions):

	<b>December 31, 2022</b>					
	<b>Less than 12 Months</b>		<b>12 Months or Greater</b>		<b>Total</b>	
	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>
U.S. government and agency securities . . . . .	\$ 61.6	\$(1.5)	\$ 69.5	\$ (4.6)	\$ 131.1	\$ (6.1)
Asset-backed securities . . . . .	103.3	(1.3)	254.6	(12.7)	357.9	(14.0)
Corporate debt securities . . . . .	189.0	(5.3)	784.8	(42.5)	973.8	(47.8)
Municipal securities . . . . .	—	—	2.5	(0.2)	2.5	(0.2)
	<u>\$353.9</u>	<u>\$(8.1)</u>	<u>\$1,111.4</u>	<u>\$(60.0)</u>	<u>\$1,465.3</u>	<u>\$(68.1)</u>

	<b>December 31, 2021</b>					
	<b>Less than 12 Months</b>		<b>12 Months or Greater</b>		<b>Total</b>	
	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>
U.S. government and agency securities . . . . .	\$ 85.1	\$ (0.7)	\$—	\$—	\$ 85.1	\$ (0.7)
Asset-backed securities . . . . .	433.3	(2.9)	—	—	433.3	(2.9)
Corporate debt securities . . . . .	1,114.1	(8.3)	—	—	1,114.1	(8.3)
	<u>\$1,632.5</u>	<u>\$(11.9)</u>	<u>\$—</u>	<u>\$—</u>	<u>\$1,632.5</u>	<u>\$(11.9)</u>

The Company reviews its investments in debt securities to determine if there has been an other-than-temporary decline in fair value. Consideration is given to 1) the length of time and the extent to which the security's fair value has been below cost, 2) the financial condition and near-term prospects of the issuer, including the credit quality of the security's issuer, 3) the Company's intent to sell the security, and 4) whether it is more likely than not the Company will have to sell the security before recovery of its amortized cost. During 2022, the decline in fair value of the debt securities was largely due to changes in interest rates, not credit quality, and as of December 31, 2022, the Company did not intend to sell the securities, and it was not more likely than not that it will be required to sell the securities, before recovery of the unrealized losses, and therefore, the unrealized losses are considered temporary.



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. INVESTMENTS (Continued)**

*Investments in Unconsolidated Entities*

The Company has a number of equity investments in unconsolidated entities. These investments are recorded in “*Long-term Investments*” on the consolidated balance sheets, and are as follows:

	December 31,	
	2022	2021
	(in millions)	
<b>Equity method investments</b>		
Carrying value of equity method investments . . . . .	\$ 21.4	\$ 8.4
<b>Equity securities</b>		
Carrying value of non-marketable equity securities . . . . .	86.9	84.1
<b>Total investments in unconsolidated entities . . . . .</b>	<u>\$108.3</u>	<u>\$92.5</u>

During 2022, the Company made \$13.2 million of equity investments in limited liability companies that invest in qualified community development entities (“CDEs”) through the New Markets Tax Credit (“NMTC”) program. The NMTC program provides federal tax incentives to investors to make investments in distressed communities and promotes economic improvements through the development of successful businesses in these communities. The NMTC is equal to 39% of the qualified investment and is taken over seven years. These limited liability companies are variable interest entities (“VIEs”). The Company determined that it is not the primary beneficiary of the VIEs because it does not have the power to direct the activities that most significantly impact the economic performance of the VIEs, and therefore the Company does not consolidate these entities. Instead, the NMTC investments are accounted for as equity method investments.

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. During 2022, the Company recorded an upward adjustment of \$0.8 million based on observable price changes and a downward adjustment of \$0.5 million due to an impairment. During 2021, the Company recorded an upward adjustment of \$4.2 million based on observable price changes. As of December 31, 2022, the Company had recorded cumulative upward adjustments of \$8.8 million based on observable price changes, and cumulative downward adjustments of \$3.1 million due to impairments and observable price changes.

During 2022, 2021, and 2020, the gross realized gains or losses from sales of available-for-sale investments were not material.

**8. ACQUISITIONS AND OTHER ARRANGEMENTS**

**In-process Research and Development Assets**

The Company acquired Harpoon Medical, Inc (“Harpoon”) on December 1, 2017 and CardiAQ Valve Technologies, Inc. (“CardiAQ”) on July 3, 2015. In-process research and development assets acquired as part of these transactions 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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. ACQUISITIONS AND OTHER ARRANGEMENTS (Continued)**

manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals.

In September 2022, the Company decided to exit the *HARPOON* program and recorded a \$28.1 million impairment charge to fully write off the in-process research and development assets. See Note 4 for further information.

The valuation for CardiAQ 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 2024.

Upon completion of development, the underlying research and development intangible assets will be amortized over their estimated useful lives.

Certain of the Company's business acquisitions involve contingent consideration arrangements. Payment of additional consideration in the future may be required, contingent upon the acquired business reaching certain performance milestones, such as attaining specified sales levels or obtaining regulatory approvals. See Note 11 for further information.

**Investments in Variable Interest Entities**

Edwards has relationships with various variable interest entities that it does not consolidate as Edwards lacks the power to direct the activities that significantly impact the economic success of these entities. The Company's maximum loss exposure to variable interest entities, prior to the exercise of options to acquire the entities, is limited to its investments in the variable interest entities, which include equity investments, options to acquire, and promissory notes.

In August 2022, the Company entered into an option agreement with a medical device company. Under the option agreement, Edwards paid \$47.1 million for an option to acquire the medical device company. The \$47.1 million option is included in "*Other Assets*" on the consolidated balance sheet.

In June 2022, the Company entered into a convertible promissory note and amended its existing warrant agreement with a medical device company. Under the convertible promissory note agreement, the Company has agreed to loan the medical device company up to \$47.5 million, of which \$32.5 million has been advanced as of December 31, 2022. In addition, the Company amended its warrant agreement under which the Company had previously paid \$35.0 million for an option to acquire the medical device company. The amendment extends the warrant right period. The \$35.0 million warrant and the \$32.5 million note receivable are included in "*Other Assets*" on the consolidated balance sheet.

In May 2022, the Company entered into an option agreement with a medical technology company. Under the option agreement, Edwards paid \$60.0 million for an option to acquire the medical technology company, of which \$10 million was paid in 2021. The \$60.0 million option is included in "*Other Assets*" on the consolidated balance sheet.

In April 2021, the Company recorded \$35.9 million, included in "*Long-term Investments*," related to its investment in a privately-held medical device company (the "Investee"), including an initial cash investment in

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. ACQUISITIONS AND OTHER ARRANGEMENTS (Continued)**

the Investee’s preferred equity securities and other consideration. Also, in April 2021, the Company paid \$5.7 million, included in “*Other Assets*,” for an option to acquire the Investee. Per the agreement, the Company may be required to invest up to an additional \$9.9 million in the Investee’s preferred equity securities and up to an additional \$21.8 million for the option to acquire the Investee, depending on the achievement of certain milestones, of which the Company invested \$10.8 million in the fourth quarter of 2021 upon achievement of the first milestone. The Company also agreed to loan the Investee up to \$45.0 million under a secured promissory note. As of December 31, 2022, there had been no borrowings under this secured promissory note.

In addition, Edwards has made equity investments through the NMTC program in limited liability companies that are considered VIEs. For more information, see Note 7.

**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 2022, the Company recorded a \$52.7 million impairment charge related to certain of its developed technology and in-process research and development assets. See Note 4 for further information.

The changes in the carrying amount of goodwill, by segment, during the years ended December 31, 2022 and 2021 were as follows:

	<u>United States</u>	<u>Europe</u>	<u>Rest of World</u>	<u>Total</u>
	(in millions)			
Goodwill at December 31, 2020 . . . . .	\$773.7	\$68.3	\$331.2	\$1,173.2
Currency translation adjustment . . . . .	—	(5.3)	—	(5.3)
Goodwill at December 31, 2021 . . . . .	<u>773.7</u>	<u>63.0</u>	<u>331.2</u>	<u>1,167.9</u>
Currency translation adjustment . . . . .	—	(3.6)	—	(3.6)
Goodwill at December 31, 2022 . . . . .	<u><u>\$773.7</u></u>	<u><u>\$59.4</u></u>	<u><u>\$331.2</u></u>	<u><u>\$1,164.3</u></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,					
		2022			2021		
		Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
<b>Finite-lived intangible assets</b>							
Patents . . . . .	8.8	\$205.5	\$(185.0)	\$ 20.5	\$185.7	\$(184.2)	\$ 1.5
Developed technology . . . . .	12.2	128.1	(57.9)	70.2	153.9	(55.5)	98.4
Other . . . . .	10.0	12.2	(7.7)	4.5	12.4	(6.8)	5.6
	11.3	345.8	(250.6)	95.2	352.0	(246.5)	105.5
<b>Indefinite-lived intangible assets</b>							
In-process research and development . . . . .		190.0	—	190.0	218.1	—	218.1
		<u>\$535.8</u>	<u>\$(250.6)</u>	<u>\$285.2</u>	<u>\$570.1</u>	<u>\$(246.5)</u>	<u>\$323.6</u>

Amortization expense related to other intangible assets for the years ended December 31, 2022, 2021, and 2020 was \$5.7 million, \$7.7 million, and \$5.4 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2023 . . . . .	\$5.6
2024 . . . . .	5.3
2025 . . . . .	4.8
2026 . . . . .	5.8
2027 . . . . .	6.2

**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, 2022 and 2021:

	December 31,			
	2022		2021	
	Amount	Effective Interest Rate	Amount	Effective Interest Rate
	(in millions)		(in millions)	
Fixed-rate 4.3% Notes . . . . .	\$600.0	4.329%	\$600.0	4.329%
Unamortized discount . . . . .	(0.9)		(1.0)	
Unamortized debt issuance costs . . . . .	(2.8)		(3.3)	
Total carrying amount . . . . .	\$596.3		\$595.7	

As of December 31, 2022 and 2021, the fair value of the Notes was \$575.2 million and \$675.4 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.

In July 2022, the Company and certain of its subsidiaries, as borrowers, entered into a new Five-Year Credit Agreement (“the New Credit Agreement”) with the lenders thereto, which provides for a \$750.0 million multi-currency unsecured revolving credit facility and replaces the Company’s prior credit agreement and related revolving credit facility. The New Credit Agreement matures on July 15, 2027. Subject to certain terms and conditions and the agreement of the lenders, the Company may increase the amount available under the New Credit Agreement by up to an additional \$250.0 million in the aggregate and extend the maturity date for an additional year. Borrowings under the New Credit Agreement bear interest at a variable rate based on the Secured Overnight Financing Rate (“SOFR”), plus a spread ranging from 0.785% to 1.3%, depending on the leverage ratio or credit rating, as defined in the agreement. The Company will also pay a facility fee ranging from 0.09% to 0.20%, depending on the Company’s leverage ratio or credit rating, on the entire credit commitment available, whether or not drawn. The facility fee is expensed as incurred. During 2022, under the New Credit Agreement, the spread over SOFR was 0.9% and the facility fee was 0.1%, and under the previous credit agreement, the spread over the London interbank offered rate was 0.9% and the facility fee was 0.1%. Issuance costs of \$2.1 million are being amortized to interest expense over the term of the New Credit Agreement. As of December 31, 2022 and 2021, there were no borrowings outstanding. Amounts outstanding under the New Credit Agreement, if any from time to time, are classified as long-term obligations in accordance with the terms of the agreement. The New Credit Agreement is unsecured and contains various financial and other covenants, including a maximum leverage ratio, as defined in the agreement. The Company was in compliance with all covenants under the New Credit Agreement at December 31, 2022.

The weighted-average interest rate under all debt obligations, including the impact of the cross currency swap contract (see Note 12), was 3.4% at both December 31, 2022 and 2021, respectively.

**11. FAIR VALUE MEASUREMENTS**

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.

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.

**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, 2022 and 2021 (in millions):

<u>December 31, 2022</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Assets</b>				
Cash equivalents . . . . .	\$ 0.4	\$ —	\$ —	\$ 0.4
Available-for-sale investments:				
Corporate debt securities . . . . .	—	980.3	—	980.3
Asset-backed securities . . . . .	—	366.6	—	366.6
United States government and agency securities . . . . .	37.1	94.5	—	131.6
Municipal securities . . . . .	—	2.5	—	2.5
Investments held for deferred compensation plans . .	112.1	—	—	112.1
Derivatives . . . . .	—	65.5	—	65.5
	<u>\$149.6</u>	<u>\$1,509.4</u>	<u>\$ —</u>	<u>\$1,659.0</u>
<b>Liabilities</b>				
Derivatives . . . . .	\$ —	\$ 27.2	\$ —	\$ 27.2
Contingent consideration liabilities . . . . .	—	—	26.2	26.2
Other liability . . . . .	—	—	14.0	14.0
	<u>\$ —</u>	<u>\$ 27.2</u>	<u>\$40.2</u>	<u>\$ 67.4</u>
 <u>December 31, 2021</u>				
<b>Assets</b>				
Cash equivalents . . . . .	\$ 15.2	\$ 30.7	\$ —	\$ 45.9
Available-for-sale investments:				
Bank time deposits . . . . .	—	2.5	—	2.5
Corporate debt securities . . . . .	—	1,390.8	—	1,390.8
Asset-backed securities . . . . .	—	512.6	—	512.6
United States government and agency securities . . . . .	28.4	118.9	—	147.3
Commercial paper . . . . .	—	127.7	—	127.7
Municipal securities . . . . .	—	2.8	—	2.8
Investments held for deferred compensation plans . .	130.7	—	—	130.7
Derivatives . . . . .	—	55.3	—	55.3
	<u>\$174.3</u>	<u>\$2,241.3</u>	<u>\$ —</u>	<u>\$2,415.6</u>
<b>Liabilities</b>				
Derivatives . . . . .	\$ —	\$ 3.9	\$ —	\$ 3.9
Contingent consideration liabilities . . . . .	—	—	62.0	62.0
Other liability . . . . .	—	—	14.0	14.0
	<u>\$ —</u>	<u>\$ 3.9</u>	<u>\$76.0</u>	<u>\$ 79.9</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. FAIR VALUE MEASUREMENTS (Continued)**

*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, United States 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.

*Deferred Compensation Plans*

The Company holds investments in a variety of money market and mutual funds related to its deferred compensation plans. The fair values of these investments 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 the derivative financial instruments 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.

*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 sales 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 as of December 31, 2022 include (1) the discount rate used to present value the projected cash flows (ranging from 3.8% to 12.8%; weighted average of 4.1%), (2) the probability of milestone achievement (ranging from 0% to 50%; weighted average of 39.6%), and (3) the projected payment dates (2026). 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.

**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 and the other liability for the years ended December 31, 2022 and 2021 (in millions):

	<u>Contingent Consideration</u>	<u>Other Liability</u>	<u>Total</u>
Fair value, December 31, 2020 .....	\$ 186.1	\$ —	\$ 186.1
Additions .....	—	14.0	14.0
Changes in fair value .....	<u>(124.1)</u>	<u>—</u>	<u>(124.1)</u>
Fair value, December 31, 2021 .....	\$ 62.0	\$14.0	\$ 76.0
Changes in fair value .....	<u>(35.8)</u>	<u>—</u>	<u>(35.8)</u>
Fair value, December 31, 2022 .....	<u>\$ 26.2</u>	<u>\$14.0</u>	<u>\$ 40.2</u>

The contingent consideration liabilities related to certain of the Company's previous business acquisitions were reduced in 2022 by \$30.9 million due to both the changes in projected probabilities of milestone achievement and the Company's decision during the third quarter of 2022 to exit its *HARPOON* surgical mitral repair system program (see Note 4). The contingent consideration liabilities were reduced in 2021 by \$123.2 million due to changes in the projected probabilities of milestone achievements and the projected timing of cash inflows from product sales.

**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.

	<u>Notional Amount</u>	
	<u>As of December 31,</u>	
	<u>2022</u>	<u>2021</u>
	(in millions)	
Foreign currency forward exchange contracts .....	\$1,678.4	\$1,498.8
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):

	<u>Balance Sheet Location</u>	<u>Fair Value</u>	
		<u>As of December 31,</u>	<u>As of December 31,</u>
		<u>2022</u>	<u>2021</u>
<b><u>Derivatives designated as hedging instruments</u></b>			
<b>Assets</b>			
Foreign currency contracts .....	Other current assets	\$24.9	\$36.2
Cross currency swap contracts .....	Other assets	\$40.6	\$19.1
<b>Liabilities</b>			
Foreign currency contracts .....	Accrued and other liabilities	\$20.7	\$ 3.9
Foreign currency contracts .....	Other liabilities	\$ 6.5	\$ —

**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
<b>December 31, 2022</b>						
<b>Derivative Assets</b>						
Foreign currency contracts . . . . .	\$24.9	\$—	\$24.9	\$(12.0)	\$—	\$12.9
Cross currency swap contracts . . . . .	\$40.6	\$—	\$40.6	\$ —	\$—	\$40.6
<b>Derivative Liabilities</b>						
Foreign currency contracts . . . . .	\$27.2	\$—	\$27.2	\$(12.0)	\$—	\$15.2
<b>December 31, 2021</b>						
<b>Derivative Assets</b>						
Foreign currency contracts . . . . .	\$36.2	\$—	\$36.2	\$ (2.8)	\$—	\$33.4
Cross currency swap contracts . . . . .	\$19.1	\$—	\$19.1	\$ —	\$—	\$19.1
<b>Derivative Liabilities</b>						
Foreign currency contracts . . . . .	\$ 3.9	\$—	\$ 3.9	\$ (2.8)	\$—	\$ 1.1

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	
	2022	2021		2022	2021
	(in millions)			(in millions)	
<b>Cash flow hedges</b>					
Foreign currency contracts . . . . .	\$81.7	\$56.7	Cost of sales	\$88.4	\$(23.0)
			Selling, general, and administrative expenses	\$ —	\$ (0.6)
	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)	
	2022	2021		2022	2021
	(in millions)			(in millions)	
<b>Net investment hedges</b>					
Cross currency swap contracts . . . . .	\$21.6	\$18.4	Interest expense	\$7.0	\$6.4

The cross currency swap contracts 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



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)**

\$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		
		2022	2021	2020
		(in millions)		
<b>Fair value hedges</b>				
Foreign currency contracts . . . . .	Other income, net	\$(3.9)	\$11.6	\$(1.4)
		(in millions)		
<b>Derivatives not designated as hedging instruments</b>				
Foreign currency contracts . . . . .	Other income, net	\$44.0	\$27.4	\$(15.1)

The following tables present 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, 2022		
	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 . . . . .	\$(1,080.4)	\$(1,567.6)	\$ 2.6
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items . . . . .	—	—	5.5
Derivatives designated as hedging instruments . . . . .	—	—	(5.5)
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach . . . . .	—	—	1.6
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income . . . . .	88.4	—	—

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)**

	<b>Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships Twelve Months Ended December 31, 2021</b>		
	<b>Cost of sales</b>	<b>Selling, general, and administrative expenses</b>	<b>Other Income, net</b>
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 . . . . .	\$(1,248.9)	\$(1,493.7)	\$12.7
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items . . . . .	—	—	(9.0)
Derivatives designated as hedging instruments . . . . .	—	—	9.0
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach . . . . .	—	—	2.6
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income . . . . .	(23.0)	(0.6)	—

The Company expects that during 2023 it will reclassify to earnings a \$29.2 million gain currently recorded in “*Accumulated Other Comprehensive Loss*.” For the years ended December 31, 2022, 2021, and 2020, 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**

The Company maintains defined benefit pension plans in Japan and certain European countries.

	<b>Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(in millions)</b>	
<b>Change in projected benefit obligation:</b>		
Beginning of year . . . . .	\$117.9	\$ 126.2
Service cost . . . . .	5.5	6.5
Interest cost . . . . .	0.5	0.4
Participant contributions . . . . .	1.6	1.5
Actuarial gain . . . . .	(22.6)	(6.1)
Benefits paid . . . . .	(0.6)	(2.5)
Plan amendment . . . . .	(0.3)	(0.5)
Settlements and curtailment gain . . . . .	(1.8)	—
Currency exchange rate changes and other . . . . .	(6.1)	(7.6)
End of year . . . . .	<u>\$ 94.1</u>	<u>\$ 117.9</u>
<b>Change in fair value of plan assets:</b>		
Beginning of year . . . . .	\$ 76.9	\$ 73.3
Actual return on plan assets . . . . .	(4.9)	5.8
Employer contributions . . . . .	3.5	3.1
Participant contributions . . . . .	1.6	1.5
Settlements . . . . .	(1.8)	—
Benefits paid . . . . .	(0.6)	(2.5)
Currency exchange rate changes and other . . . . .	(4.1)	(4.3)
End of year . . . . .	<u>\$ 70.6</u>	<u>\$ 76.9</u>
<b>Funded Status</b>		
Projected benefit obligation . . . . .	\$(94.1)	\$(117.9)
Plan assets at fair value . . . . .	70.6	76.9
Underfunded status . . . . .	<u>\$(23.5)</u>	<u>\$ (41.0)</u>
<b>Net amounts recognized on the consolidated balance sheet:</b>		
Other liabilities . . . . .	<u>\$ 23.5</u>	<u>\$ 41.0</u>
Accumulated other comprehensive loss, net of tax:		
Net actuarial gain (loss) . . . . .	\$ 1.5	\$ (16.4)
Net prior service credit . . . . .	5.3	6.0
Deferred income tax (expense) benefit . . . . .	(1.1)	2.4
Total . . . . .	<u>\$ 5.7</u>	<u>\$ (8.0)</u>

The accumulated benefit obligation (“ABO”) for all defined benefit pension plans was \$86.7 million and \$113.3 million as of December 31, 2022 and 2021, respectively. The projected benefit obligation and ABO were in excess of plan assets for all pension plans as of December 31, 2022 and 2021.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**13. EMPLOYEE BENEFIT PLANS (Continued)**

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

	<b>Years Ended December 31,</b>		
	<b><u>2022</u></b>	<b><u>2021</u></b>	<b><u>2020</u></b>
Service cost, net . . . . .	\$ 5.5	\$ 6.5	\$ 6.3
Interest cost . . . . .	0.5	0.4	0.5
Expected return on plan assets . . . . .	(1.5)	(1.1)	(1.0)
Settlements and curtailment gain . . . . .	0.1	—	—
Amortization of actuarial loss . . . . .	0.5	1.7	1.6
Amortization of prior service credit . . . . .	(0.7)	(0.7)	(0.7)
Net periodic pension benefit cost . . . . .	<u>\$ 4.4</u>	<u>\$ 6.8</u>	<u>\$ 6.7</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:

	<b>December 31,</b>	
	<b><u>2022</u></b>	<b><u>2021</u></b>
Discount rate . . . . .	2.5%	0.5%
Rate of compensation increase . . . . .	2.9%	2.6%
Cash balance interest crediting rate . . . . .	1.5%	2.5%
Social securities increase . . . . .	1.8%	1.6%
Pension increase . . . . .	2.2%	1.8%

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

	<b>Years ended December 31,</b>		
	<b><u>2022</u></b>	<b><u>2021</u></b>	<b><u>2020</u></b>
Discount rate . . . . .	0.5%	0.3%	0.5%
Expected return on plan assets . . . . .	2.1%	1.5%	1.5%
Rate of compensation increase . . . . .	2.6%	2.6%	2.7%
Cash balance interest crediting rate . . . . .	1.5%	2.5%	1.5%
Social securities increase . . . . .	1.6%	1.6%	1.6%
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, 2022, by asset category, are as follows:

Equity securities .....	30.7%
Debt securities .....	41.5%
Real estate .....	10.7%
Other .....	<u>17.1%</u>
Total .....	<u>100.0%</u>

The fair values of the Company's defined benefit plan assets at December 31, 2022 and 2021, by asset category, are as follows (in millions):

<u>December 31, 2022</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Asset Category</b>				
Cash .....	\$ 3.6	\$ —	\$ —	\$ 3.6
Equity securities:				
United States equities .....	1.5	—	—	1.5
International equities .....	17.5	—	—	17.5
Debt securities:				
United States government bonds .....	4.4	—	—	4.4
International government bonds .....	25.6	—	—	25.6
Real estate .....	—	7.6	—	7.6
Mortgages .....	—	3.5	—	3.5
Insurance contracts .....	—	—	0.8	0.8
Total plan assets measured at fair value .....	<u>\$52.6</u>	<u>\$11.1</u>	<u>\$ 0.8</u>	<u>\$64.5</u>
Alternative investments measured at net asset value (a) .....				6.1
Total plan assets .....				<u>\$70.6</u>



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**13. EMPLOYEE BENEFIT PLANS (Continued)**

<u>December 31, 2021</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Asset Category</b>				
Cash .....	\$ 5.4	\$ —	\$ —	\$ 5.4
Equity securities:				
United States equities .....	1.6	—	—	1.6
International equities .....	16.3	—	—	16.3
Debt securities:				
United States government bonds .....	6.2	—	—	6.2
International government bonds .....	26.3	—	—	26.3
Real estate .....	—	7.6	—	7.6
Mortgages .....	—	3.5	—	3.5
Insurance contracts .....	—	—	0.9	0.9
Total plan assets .....	<u>\$55.8</u>	<u>\$11.1</u>	<u>\$ 0.9</u>	<u>\$67.8</u>
Alternative investments measured at net asset value (a) .....				<u>9.1</u>
Total plan assets .....				<u>\$76.9</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.

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, 2022 and 2021 (in millions):

	<u>Insurance Contracts</u>
Balance at December 31, 2020 .....	\$ 1.0
Currency exchange rate impact .....	<u>(0.1)</u>
Balance at December 31, 2021 .....	0.9
Actual return on plan assets:	
Relating to assets still held at December 31, 2022 .....	0.2
Purchases, sales and settlements .....	<u>(0.2)</u>
Currency exchange rate impact .....	<u>(0.1)</u>
Balance at December 31, 2022 .....	<u>\$ 0.8</u>

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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**13. EMPLOYEE BENEFIT PLANS (Continued)**

The following benefit payments, which reflect expected future service, as appropriate, at December 31, 2022, are expected to be paid (in millions):

2023	\$ 7.1
2024	5.2
2025	5.3
2026	6.4
2027	7.6
2028-2032	36.4

As of December 31, 2022, expected employer contributions for 2023 are \$2.4 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 \$45.1 million, \$38.6 million, and \$36.6 million in 2022, 2021, and 2020, 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 participant with a return based on investment alternatives selected by the participant. The amount accrued under these nonqualified plans was \$112.6 million and \$130.9 million at December 31, 2022 and 2021, respectively.

**14. COMMON STOCK**

**Treasury Stock**

In May 2021, 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. In July 2022, the Board of Directors approved an additional \$1.5 billion of repurchases of the Company’s common stock under this program, effective July 28, 2022. The repurchase program does not have an expiration date. Stock repurchased under these programs 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 2022, 2021, and 2020, the Company repurchased 20.1 million, 5.8 million, and 3.1 million shares, respectively, at an aggregate cost of \$1,727.1 million, \$512.8 million, and \$625.4 million, respectively, including shares purchased under a Rule 10b5-1 trading plan, 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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. COMMON STOCK (Continued)**

*Accelerated Share Repurchase*

During 2022 and 2021, 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 applicable 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>Initial Delivery</u>				<u>Final Settlement</u>		
	<u>Amount Paid</u>	<u>Shares Received</u>	<u>Price per Share</u>	<u>Value of Shares as % of Contract Value</u>	<u>Settlement Date</u>	<u>Total Shares Received</u>	<u>Average Price per Share</u>
February 2021 .....	\$250.0	2.4	\$ 83.86	80%	March 2021	3.0	\$ 84.51
January 2022 .....	\$250.0	1.9	\$104.87	80%	February 2022	2.3	\$110.31
October 2022 .....	\$750.0	8.3	\$ 72.43	80%	December 2022	10.3	\$ 72.91

The ASR agreements were each 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 contracts indexed to the Company's common stock met all the applicable criteria for equity classification and, therefore, were not accounted for as a derivative instrument.

**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, typically 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. Under the Program, the number of shares of common stock authorized 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 \$0.3 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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. COMMON STOCK (Continued)**

The Company has an employee stock purchase plan for United States employees and a plan for employees outside of the United States (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 15% 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 of 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 50.4 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 United States 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%.

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

***Option Awards***

	<b>Years Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
Risk-free interest rate . . . . .	3.0%	0.8%	0.3%
Expected dividend yield . . . . .	None	None	None
Expected volatility . . . . .	31.4%	33.5%	33.4%
Expected term (years) . . . . .	5.0	5.0	5.0
Fair value, per share . . . . .	\$34.59	\$28.90	\$21.70

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

***ESPP***

	<b>Years Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
Risk-free interest rate . . . . .	0.5%	0.1%	1.3%
Expected dividend yield . . . . .	None	None	None
Expected volatility . . . . .	32.0%	36.6%	33.1%
Expected term (years) . . . . .	0.6	0.6	0.6
Fair value, per share . . . . .	\$28.18	\$23.07	\$16.61

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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. COMMON STOCK (Continued)**

The weighted-average assumptions used to determine the fair value of the market-based restricted stock units during the years ended December 31, 2022, 2021, and 2020 included a risk-free interest rate of 2.9%, 0.4%, and 0.2%, respectively, and an expected volatility rate of 33.9%, 34.4%, and 32.7%, respectively.

Stock option activity during the year ended December 31, 2022 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>
<b>Outstanding as of December 31, 2021</b> .....	12.3	\$ 52.84		
Options granted .....	1.6	104.52		
Options exercised .....	(2.1)	30.47		
Options forfeited .....	<u>(0.2)</u>	82.81		
<b>Outstanding as of December 31, 2022</b> .....	<u>11.6</u>	63.67	3.4 years	\$204.5
<b>Exercisable as of December 31, 2022</b> .....	<u>7.9</u>	51.28	2.5 years	\$197.3
<b>Vested and expected to vest as of December 31, 2022</b> ...	<u>11.1</u>	62.43	3.3 years	\$203.5

The following table summarizes nonvested restricted stock unit activity during the year ended December 31, 2022 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	<u>Shares</u>	<u>Weighted-Average Grant-Date Fair Value</u>
<b>Nonvested as of December 31, 2021</b> .....	2.3	\$ 73.94
Granted (a) .....	0.9	102.26
Vested .....	(1.1)	64.04
Forfeited .....	<u>(0.1)</u>	83.04
<b>Nonvested as of December 31, 2022</b> .....	<u>2.0</u>	92.30

(a) The shares granted include 0.1 million shares of market-based restricted stock units granted during 2022, 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, 2022, 2021, and 2020 were \$264.5 million, \$359.8 million, and \$323.5 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, 2022, 2021, and 2020, the Company received cash from exercises of stock options of \$64.8 million, \$82.2 million, and \$79.2 million, respectively, and tax benefits from exercises of stock options and vesting of restricted stock units of \$56.9 million, \$76.5 million, and \$72.1 million, respectively. The total grant-date fair value of stock options

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. COMMON STOCK (Continued)**

vested during the years ended December 31, 2022, 2021, and 2020 were \$40.4 million, \$36.2 million, and \$34.0 million, respectively.

As of December 31, 2022, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units, market-based restricted stock units, and employee stock purchase plan subscription awards amounted to \$195.1 million, which will be amortized on a straight-line basis over each award's requisite service period. The weighted-average remaining requisite service period is 31 months.

**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, 2022, 2021, and 2020.

	Foreign Currency Translation Adjustments	Unrealized Gain (Loss) on Hedges	Unrealized Gain (Loss) on Available-for-sale Investments  (in millions)	Unrealized Pension (Costs) Credits (a)	Total Accumulated Other Comprehensive Loss
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)	3.1	13.8	(1.4)	0.4	15.9
December 31, 2020	(122.4)	(27.7)	8.6	(19.6)	(161.1)
Other comprehensive (loss) income before reclassifications	(39.2)	66.3	(29.2)	12.8	10.7
Amounts reclassified from accumulated other comprehensive loss	(6.4)	12.0	8.6	1.0	15.2
Deferred income tax (expense) benefit	(4.5)	(20.9)	5.1	(2.2)	(22.5)
December 31, 2021	(172.5)	29.7	(6.9)	(8.0)	(157.7)
Other comprehensive (loss) income before reclassifications	(33.9)	75.2	(77.9)	17.3	(19.3)
Amounts reclassified from accumulated other comprehensive loss	(7.0)	(84.5)	18.8	(0.1)	(72.8)
Deferred income tax (expense) benefit	(5.4)	3.4	0.4	(3.5)	(5.1)
December 31, 2022	<u>\$(218.8)</u>	<u>\$ 23.8</u>	<u>\$(65.6)</u>	<u>\$ 5.7</u>	<u>\$(254.9)</u>



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. ACCUMULATED OTHER COMPREHENSIVE LOSS (Continued)**

(a) For the years ended December 31, 2022, 2021, and 2020, 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>
<b><u>2022</u></b>			
Prior service credit arising during period . . . . .	\$ —	\$(1.1)	\$(1.1)
Amortization of prior service credit . . . . .	<u>(0.7)</u>	<u>0.3</u>	<u>(0.4)</u>
Net prior service cost arising during period . . . . .	(0.7)	(0.8)	(1.5)
Net actuarial gain arising during period . . . . .	<u>17.9</u>	<u>(2.7)</u>	<u>15.2</u>
Unrealized pension credits, net . . . . .	<u>\$17.2</u>	<u>\$(3.5)</u>	<u>\$13.7</u>
<b><u>2021</u></b>			
Prior service credit arising during period . . . . .	\$ 0.1	\$—	\$ 0.1
Amortization of prior service credit . . . . .	<u>(0.7)</u>	<u>0.1</u>	<u>(0.6)</u>
Net prior service cost arising during period . . . . .	(0.6)	0.1	(0.5)
Net actuarial gain arising during period . . . . .	<u>14.4</u>	<u>(2.3)</u>	<u>12.1</u>
Unrealized pension credits, net . . . . .	<u>\$13.8</u>	<u>\$(2.2)</u>	<u>\$11.6</u>
<b><u>2020</u></b>			
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>\$ (4.6)</u>	<u>\$ 0.4</u>	<u>\$ (4.2)</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
	2022	2021	
Foreign currency translation adjustments . . . . .	\$ 7.0	\$ 6.4	Other income, net
	(1.7)	(1.6)	Provision for income taxes
	<u>\$ 5.3</u>	<u>\$ 4.8</u>	Net of tax
Gain (loss) on hedges . . . . .	\$ 88.4	\$(23.0)	Cost of sales
	—	(0.6)	Selling, general, and administrative expenses
	(3.9)	11.6	Other income, net
	<u>84.5</u>	<u>(12.0)</u>	Total before tax
	(22.2)	4.6	Provision for income taxes
	<u>\$ 62.3</u>	<u>\$ (7.4)</u>	Net of tax
Gain (loss) on available-for-sale investments . . . . .	\$(18.8)	\$ (8.6)	Other income, net
	4.6	2.1	Provision for income taxes
	<u>\$(14.2)</u>	<u>\$ (6.5)</u>	Net of tax
Amortization of pension adjustments . . . . .	\$ 0.1	\$ (1.0)	Other income, net
	—	0.1	Provision for income taxes
	<u>\$ 0.1</u>	<u>\$ (0.9)</u>	Net of tax

**16. OTHER INCOME, NET**

	Years Ended December 31,		
	2022	2021	2020
	(in millions)		
Foreign exchange losses (gains), net . . . . .	\$ 1.2	\$ (5.0)	\$(12.3)
Gain on insurance settlement . . . . .	(3.8)	—	—
Loss (gain) on investments . . . . .	1.1	(5.8)	(0.6)
Non-service cost components of net periodic pension benefit cost . . . . .	(1.1)	0.3	0.4
Other . . . . .	—	(2.2)	1.0
Total other income, net . . . . .	<u>\$(2.6)</u>	<u>\$(12.7)</u>	<u>\$(11.5)</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 operations in the United States and outside of the United States as follows (in millions):

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
United States .....	\$ 634.4	\$ 610.9	\$151.3
Outside of the United States, including Puerto Rico .....	1,133.0	1,091.1	765.4
	<u>\$1,767.4</u>	<u>\$1,702.0</u>	<u>\$916.7</u>

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

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
<b>Current</b>			
United States:			
Federal .....	\$ 369.1	\$125.2	\$ 23.4
State and local .....	60.6	25.1	48.2
Outside of the United States, including Puerto Rico ...	66.7	92.6	73.9
Current income tax expense .....	<u>\$ 496.4</u>	<u>\$242.9</u>	<u>\$145.5</u>
<b>Deferred</b>			
United States:			
Federal .....	\$(187.7)	\$ (9.4)	\$ 11.0
State and local .....	(58.9)	(25.4)	(32.9)
Outside of the United States, including Puerto Rico ...	(4.3)	(9.2)	(30.3)
Deferred income tax benefit .....	<u>(250.9)</u>	<u>(44.0)</u>	<u>(52.2)</u>
<b>Total income tax provision</b> .....	<u>\$ 245.5</u>	<u>\$198.9</u>	<u>\$ 93.3</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):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Deferred tax assets</b>		
Capitalized research and development expenses <sup>(a)</sup> . . . .	\$ 199.7	\$ —
Compensation and benefits . . . . .	100.6	109.8
Benefits from uncertain tax positions . . . . .	42.1	33.9
Net tax credit carryforwards . . . . .	160.8	142.0
Net operating loss carryforwards . . . . .	71.7	69.4
Accrued liabilities . . . . .	93.7	108.0
Inventories . . . . .	11.9	13.5
Cash flow and net investment hedges . . . . .	6.6	—
State income taxes . . . . .	0.3	0.4
Investments . . . . .	0.6	0.7
Lease liability obligations . . . . .	6.7	6.6
Other . . . . .	1.9	1.3
Total deferred tax assets . . . . .	<u>696.6</u>	<u>485.6</u>
<b>Deferred tax liabilities</b>		
Property, plant, and equipment . . . . .	(80.2)	(64.1)
Cash flow and net investment hedges . . . . .	—	(6.4)
Deferred tax on foreign earnings . . . . .	(19.2)	(26.3)
Right-of-use assets . . . . .	(6.0)	(6.1)
Other intangible assets . . . . .	(19.9)	(75.5)
Other . . . . .	(2.9)	(2.6)
Total deferred tax liabilities . . . . .	<u>(128.2)</u>	<u>(181.0)</u>
<b>Valuation allowance</b> . . . . .	<u>(99.1)</u>	<u>(82.5)</u>
<b>Net deferred tax assets</b> . . . . .	<u>\$ 469.3</u>	<u>\$ 222.1</u>

(a) As required by the 2017 Tax Cuts and Jobs Act, effective January 1, 2022, the Company's research and development expenditures were capitalized and amortized which resulted in substantially higher cash paid for taxes in 2022 with an equal amount of deferred tax benefits.

During 2022, net deferred tax assets increased \$247.2 million, including items that were recorded to stockholders' equity and which did not impact the Company's income tax provision.

The valuation allowance of \$99.1 million as of December 31, 2022 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, 2022 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 . . . . .	\$ 8.6	\$ 1.8	\$ —	\$ 1.8	2033-2037
United States federal net operating losses . . . . .	11.3	2.4	—	2.4	Indefinite
United States state net operating losses . . . . .	35.7	1.8	(1.7)	0.1	2026-2041
United States state net operating losses . . . . .	2.6	0.1	(0.1)	—	Indefinite
Non-United States net operating losses . . . . .	390.5	65.5	(50.6)	14.9	Indefinite
United States capital losses . . . . .	33.4	0.1	(0.1)	—	2024
Total . . . . .	<u>\$482.1</u>	<u>\$71.7</u>	<u>\$(52.5)</u>	<u>\$19.2</u>	

Certain tax attributes are subject to an annual limitation as a result of the acquisition of CASMED, 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, 2022 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 . . . . .	\$189.8	\$ —	\$189.8	Indefinite
Federal research expenditure tax credits . . . . .	1.3	—	1.3	2026-2039
Foreign tax and general business credits . . . . .	4.3	(3.8)	0.5	2030-2032
Puerto Rico purchases credits . . . . .	26.4	(26.4)	—	Indefinite
Total . . . . .	<u>\$221.8</u>	<u>\$(30.2)</u>	<u>\$191.6</u>	

The Company has \$189.8 million of gross 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 into the distant future. Accordingly, no valuation allowance has been provided. The Company has \$26.4 million of Puerto Rico purchases credits. Throughout its history and into the future, the Company's 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 currently have an indefinite life, the Company continues to record a valuation allowance on the purchases credits carryforwards. The Company recently renegotiated its tax grant under Puerto Rico Act 52-2022 ("Act 52") effective January 1, 2023. Among other items, Act 52 introduced new requirements and limitations on the availability and claiming of tax credits. As a result, the Company now expects that its purchases credits may begin to expire after 2026.

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 United States 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. The Company elected to pay the repatriation tax in installments over eight years.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

The Company asserts that \$1.0 billion of its foreign earnings continue to be indefinitely reinvested and it intends to repatriate \$580.8 million of its foreign earnings as of December 31, 2022. The estimated net tax liability on the indefinitely reinvested earnings if repatriated is \$14.9 million.

The Company has received tax incentives in certain non-United States tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were \$247.4 million (\$0.40 per diluted share), \$208.0 million (\$0.33 per diluted share), and \$189.2 million (\$0.30 per diluted share) for the years ended December 31, 2022, 2021, and 2020, 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):

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Income tax expense at United States federal statutory rate . . . . .	\$ 371.1	\$ 357.4	\$192.5
Foreign income taxed at different rates . . . . .	(123.9)	(122.2)	(80.5)
State and local taxes, net of federal tax benefit . . . . .	21.1	11.9	5.0
Tax credits, federal and state . . . . .	(50.0)	(48.4)	(43.1)
Build of reserve for prior years' uncertain tax positions . . . . .	11.6	3.6	4.2
Tax on global intangible low-taxed income . . . . .	61.4	56.5	49.2
Foreign-derived intangible income deduction . . . . .	(15.0)	(1.3)	(2.6)
Contingent consideration liabilities . . . . .	(7.5)	(26.1)	2.9
United States federal deductible employee share-based compensation . . . . .	(31.6)	(47.8)	(48.3)
Nondeductible employee share-based compensation . . . . .	5.8	5.3	4.2
Other . . . . .	2.5	10.0	9.8
Income tax provision . . . . .	<u>\$ 245.5</u>	<u>\$ 198.9</u>	<u>\$ 93.3</u>

The Company's effective tax rate for 2022 increased in comparison to 2021 primarily due to the decrease in the tax benefit from the change in fair value of contingent consideration liabilities and the decrease in the excess tax benefit from employee share-based compensation. The Company's effective tax rate for 2021 increased in comparison to 2020 primarily due to the tax benefit from the Settlement Agreement with Abbott in 2020 (see Note 3) and the decrease in the excess tax benefit from employee share-based compensation, partially offset by the tax benefit from the change in fair value of contingent consideration liabilities.

Uncertain Tax Positions

As of December 31, 2022 and 2021, the gross uncertain tax positions were \$475.3 million and \$358.4 million, respectively. The Company estimates that these liabilities would be reduced by \$182.1 million and \$135.1 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 \$293.2 million and \$223.3 million, respectively, if not required, would favorably affect the Company's effective tax rate.



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

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,		
	2022	2021	2020
Uncertain gross tax positions, January 1 . . . . .	\$358.4	\$281.8	\$203.1
Current year tax positions . . . . .	120.6	82.1	86.4
Increase in prior year tax positions . . . . .	3.8	2.3	6.0
Decrease in prior year tax positions . . . . .	(0.6)	(4.8)	(10.0)
Settlements . . . . .	(0.4)	(0.3)	(3.7)
Lapse of statutes of limitations . . . . .	(6.5)	(2.7)	—
Uncertain gross tax positions, December 31 . . . . .	\$475.3	\$358.4	\$281.8

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, 2022, the Company had accrued \$29.1 million (net of \$15.4 million tax benefit) of interest related to uncertain tax positions, and as of December 31, 2021, the Company had accrued \$19.5 million (net of \$8.1 million tax benefit) of interest related to uncertain tax positions. During 2022, 2021, and 2020, the Company recognized interest expense, net of tax benefit, of \$9.6 million, \$5.2 million, and \$5.0 million, respectively, in “*Provision for Income Taxes*” on the consolidated statements of operations.

In the normal course of business, the Internal Revenue Service (“IRS”) and other taxing authorities are in different stages of examining various years of the Company’s tax filings. During these audits, the Company may receive proposed audit adjustments that could be material. Therefore, there is a possibility that an adverse outcome in these audits could have a material effect on the Company’s results of operations and financial condition. 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 for any adjustments that may result from these uncertain tax positions.

At December 31, 2022, 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 India for years from 2010 and on.

The Company executed an Advance Pricing Agreement (“APA”) in 2018 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 (collectively “Surgical/TAVR”) intercompany royalty transactions, then reverted to IRS

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

examination for further consideration as part of the respective years' regular tax audits. In addition, the Company executed other bilateral 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 all of the APAs which cover transactions with Japan for the years 2020 and forward. An APA between Switzerland and Japan covering tax years 2020 through 2024 was executed in 2021. The execution of the other APA renewals depends on many variables outside of the Company's control.

The audits of the Company's United States federal income tax returns through 2014 have been closed. The IRS audit field work for the 2015 through 2017 tax years was completed during the second quarter of 2021, except for transfer pricing and related matters. The IRS began its examination of the 2018 through 2020 tax years during the first quarter of 2022.

During 2021, the Company received a Notice of Proposed Adjustment ("NOPA") from the IRS for the 2015-2017 tax years relating to transfer pricing involving certain Surgical/TAVR intercompany royalty transactions between the Company's United States and Switzerland subsidiaries. The NOPA proposes an increase to the Company's United States taxable income, which could result in additional tax expense for this period of approximately \$210 million and represents a significant change to previously agreed upon transfer pricing methodologies for these types of transactions. The Company has formally disagreed with the NOPA and submitted a formal protest on the matter during the fourth quarter of 2021. During the second quarter of 2022, the Company received the IRS's rebuttal to its protest and was notified that the case has been transferred to the IRS Independent Office of Appeals. The opening conference is scheduled for the first quarter of 2023. The Company continues to evaluate all possible remedies available to it, which could take several years to resolve. The Company believes the amounts previously accrued related to this uncertain tax position are sufficient and, accordingly, has not accrued any additional amount based on the NOPA received. While no payment of any amount related to the NOPA is required to be made, if at all, until all applicable proceedings have been completed, the Company made an advance payment of tax in November 2022 to prevent the further accrual of interest on any potential deficiency.

Certain Surgical/TAVR intercompany royalty transactions covering tax years 2015 through 2022 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, 2022. The Company has considered this information, as well as information regarding the NOPA and rebuttal described above, in its evaluation of its uncertain tax positions. The impact of 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 in its existing uncertain tax positions may occur in the next 12 months and, therefore, has continued to record the uncertain tax positions as a long-term liability.

**18. LEGAL PROCEEDINGS**

The Company is reviewing and investigating whether business activities in Japan and other markets violate certain provisions of the Foreign Corrupt Practices Act ("FCPA"). The Company voluntarily notified the SEC and the United States Department of Justice ("DOJ") during 2021 that it has engaged outside counsel to conduct this review and investigation. The Company has provided status updates to the SEC and DOJ since that time. Any determination that the Company's operations or activities are not in compliance with existing laws, including the FCPA, could result in the imposition of fines, penalties, and equitable remedies. The Company cannot currently predict the outcome of the review and investigation or the potential impact on its financial statements.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**18. LEGAL PROCEEDINGS (Continued)**

On September 28, 2021, Aortic Innovations LLC, a non-practicing entity, filed a lawsuit against Edwards Lifesciences Corporation and certain of its subsidiaries (“Edwards”) in the United States District Court for the District of Delaware alleging that Edwards’ *SAPIEN 3 Ultra* product infringes certain of its patents. The Company is unable to predict the ultimate outcome of this matter or estimate a range of possible exposure; therefore, no amounts have been accrued. The Company intends to vigorously defend itself in this litigation.

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 “Lawsuits”). The 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 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 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 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 sanctions are involved is \$1 million.

**19. SEGMENT INFORMATION**

Edwards Lifesciences 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 the same as those described in Note 2. Segment net sales and segment operating income are based on internally derived foreign exchange rates 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. There were no customers that represented 10% or more of the Company’s total net sales.

Certain items are maintained at the corporate level and are not allocated to the segments. The non-allocated items include net interest income, 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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**19. SEGMENT INFORMATION (Continued)**

impractical to determine the amount of depreciation expense included in each segment, and, therefore, a portion 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):

	<b>Years Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
<b>Segment Net Sales</b>			
United States . . . . .	\$3,132.6	\$2,963.1	\$2,516.8
Europe . . . . .	1,213.7	1,099.6	945.2
Japan . . . . .	559.3	528.0	448.6
Rest of World . . . . .	610.7	533.2	451.5
Total segment net sales . . . . .	<u>\$5,516.3</u>	<u>\$5,123.9</u>	<u>\$4,362.1</u>
<b>Segment Operating Income</b>			
United States . . . . .	\$2,130.9	\$2,051.0	\$1,727.3
Europe . . . . .	652.2	569.1	479.3
Japan . . . . .	376.7	348.0	286.4
Rest of World . . . . .	247.7	185.2	150.1
Total segment operating income . . . . .	<u>\$3,407.5</u>	<u>\$3,153.3</u>	<u>\$2,643.1</u>

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

	<b>Years Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
<b>Net Sales Reconciliation</b>			
Segment net sales . . . . .	\$ 5,516.3	\$ 5,123.9	\$ 4,362.1
Foreign currency . . . . .	(133.9)	108.6	24.2
Consolidated net sales . . . . .	<u>\$ 5,382.4</u>	<u>\$ 5,232.5</u>	<u>\$ 4,386.3</u>
<b>Pre-tax Income Reconciliation</b>			
Segment operating income . . . . .	\$ 3,407.5	\$ 3,153.3	\$ 2,643.1
Unallocated amounts:			
Corporate items . . . . .	(1,714.1)	(1,613.8)	(1,358.0)
Special charge . . . . .	(60.7)	—	—
Intellectual property litigation expenses, net . . .	(15.8)	(20.6)	(405.4)
Change in fair value of contingent consideration liabilities, net . . . . .	35.8	124.1	(13.6)
Foreign currency . . . . .	95.8	47.3	31.5
Consolidated operating income . . . . .	<u>1,748.5</u>	<u>1,690.3</u>	<u>897.6</u>
Non-operating income . . . . .	18.9	11.7	19.1
Consolidated pre-tax income . . . . .	<u>\$ 1,767.4</u>	<u>\$ 1,702.0</u>	<u>\$ 916.7</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**19. SEGMENT INFORMATION (Continued)**

**Enterprise-Wide Information**

(in millions)

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,		
	2022	2021	2020
<b>Net Sales by Geographic Area</b>			
United States .....	\$3,132.6	\$2,963.1	\$2,516.8
Europe .....	1,174.8	1,190.3	973.6
Japan .....	473.6	528.9	460.1
Rest of World .....	601.4	550.2	435.8
	<u>\$5,382.4</u>	<u>\$5,232.5</u>	<u>\$4,386.3</u>
<b>Net Sales by Major Product Area</b>			
Transcatheter Aortic Valve Replacement .....	\$3,518.2	\$3,422.5	\$2,857.3
Transcatheter Mitral and Tricuspid Therapies ....	116.1	86.0	41.8
Surgical Structural Heart .....	893.1	889.1	761.8
Critical Care .....	855.0	834.9	725.4
	<u>\$5,382.4</u>	<u>\$5,232.5</u>	<u>\$4,386.3</u>
<b>Long-lived Tangible Assets by Geographic Area</b>			
United States .....	\$1,188.5	\$1,195.8	\$1,084.3
Europe .....	191.8	197.9	192.7
Japan .....	13.2	19.7	20.4
Rest of World .....	331.6	335.5	311.0
	<u>\$1,725.1</u>	<u>\$1,748.9</u>	<u>\$1,608.4</u>

**20. 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, 2022					
Allowance for credit losses (a) .....	\$15.7	\$ 0.9	\$ 0.1	\$(5.0)	\$11.7
Tax valuation allowance (b) .....	82.5	3.0	14.2	(0.6)	99.1
Year ended December 31, 2021					
Allowance for credit losses (a) .....	\$16.4	\$ 1.2	\$ 0.6	\$(2.5)	\$15.7
Tax valuation allowance (b) .....	71.6	12.4	—	(1.5)	82.5
Year ended December 31, 2020					
Allowance for credit losses (a) .....	\$14.7	\$ 3.1	\$ —	\$(1.4)	\$16.4
Tax valuation allowance (b) .....	65.8	6.3	0.6	(1.1)	71.6

(a) The deductions related to allowances for credit losses represent accounts receivable which are written off.

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**20. VALUATION AND QUALIFYING ACCOUNTS (Continued)**

- (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.



**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) or 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2022.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded as of December 31, 2022 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, 2022. The effectiveness of the Company's internal control over financial reporting as of December 31, 2022 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 2022 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other Information**

None.

**Item 9C. Information Regarding Foreign Jurisdictions That Prevent Inspections**

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 2023 Annual Meeting of Stockholders (the “Proxy Statement”) (which Proxy Statement will be filed with the SEC within 120 days of December 31, 2022). 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 <https://ir.edwards.com> under “Governance & Sustainability—Corporate Responsibility & Sustainability—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 “Board of Directors Matters—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 July 15, 2021 (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences’ report on Form 8-K filed on July 15, 2021)
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 (incorporated by reference to Exhibit 4.2 in Edwards Lifesciences’ report on Form 10-K for the fiscal year ended December 31, 2022)
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	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”)
4.5	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 July 15, 2022, among Edwards Lifesciences Corporation and certain of its subsidiaries, as Borrowers, the lenders signatory thereto, Bank of America, N.A., as Administrative Agent (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences’ report on Form 8-K filed on July 21, 2022)
#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)
*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)

Exhibit No.	Description
*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	Description of Severance Benefits for Mr. Jean-Luc Lemercier (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2021)
*10.8	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)
*10.9	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)
*10.10	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)
*10.11	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 10.11 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*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 10.12 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*10.13	Edwards Lifesciences Corporation Form of Long-Term Stock Incentive Compensation Program Global Performance-Based Restricted Stock Unit Award Agreement for awards granted beginning May 2015 (incorporated by reference to Exhibit 10.13 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*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 Exhibit 10.15 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*10.16	Edwards Lifesciences Corporation Form of Participant Stock Option Statement and related Nonemployee Directors Stock Incentive Program Nonqualified Stock Option Award Agreement (incorporated by reference to Exhibit 10.16 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)

Exhibit No.	Description
*10.17	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Units Agreement (incorporated by reference to Exhibit 10.17 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*10.18	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Agreement (incorporated by reference to Exhibit 10.18 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*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 13, 2023

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 13, 2023
<u>                    /s/ SCOTT B. ULLEM                    </u> Scott B. Ullem	Corporate Vice President, Chief Financial Officer (Principal Financial Officer)	February 13, 2023
<u>                    /s/ ROBERT W.A. SELLERS                    </u> Robert W.A. Sellers	Senior Vice President, Corporate Controller (Principal Accounting Officer)	February 13, 2023
<u>                    /s/ KIERAN T. GALLAHUE                    </u> Kieran T. Gallahue	Director	February 13, 2023
<u>                    /s/ LESLIE S. HEISZ                    </u> Leslie S. Heisz	Director	February 13, 2023
<u>                    /s/ PAUL A. LAVIOLETTE                    </u> Paul A. LaViolette	Director	February 13, 2023
<u>                    /s/ STEVEN R. LORANGER                    </u> Steven R. Loranger	Director	February 13, 2023
<u>                    /s/ MARTHA H. MARSH                    </u> Martha H. Marsh	Director	February 13, 2023
<u>                    /s/ RAMONA SEQUEIRA                    </u> Ramona Sequeira	Director	February 13, 2023
<u>                    /s/ NICHOLAS J. VALERIANI                    </u> Nicholas J. Valeriani	Director	February 13, 2023



**Exhibit 21.1**

The following is a list of subsidiaries of Edwards Lifesciences Corporation, omitting subsidiaries which, considered in the aggregate as a single subsidiary, would not constitute a significant subsidiary as of December 31, 2022:

<u>Legal Entity</u>	<u>State of Incorporation/ Formation</u>	<u>Country of Incorporation/ Formation</u>
Edwards Lifesciences LLC .....	Delaware	U.S.
Edwards Lifesciences (U.S.) Inc. ....	Delaware	U.S.
Edwards Lifesciences (Japan) Limited .....		Japan

**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, 333-217909, 333-255853, and 333-255854) and Form S-3 (No. 333-266272) of Edwards Lifesciences Corporation of our report dated February 13, 2023 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 13, 2023



**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 13, 2023

**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, 2022 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.

February 13, 2023

/s/ MICHAEL A. MUSSALLEM

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

February 13, 2023

/s/ SCOTT B. ULLEM

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

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# 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 Annual Meeting of Stockholders will be held on May 11, 2023 at 10:00 am (Pacific) at the offices of Edwards Lifesciences Corporation.

## 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 website – [ir.edwards.com](http://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](mailto: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](http://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

**Steven R. Loranger**  
Former Chairman, President  
& Chief Executive Officer,  
ITT Corporation

**Martha H. Marsh**  
Former President &  
Chief Executive Officer,  
Stanford Hospital & Clinics

**Ramona Sequeira**  
President,  
Global Portfolio Division,  
Takeda Pharmaceutical USA, Inc.

**Nicholas J. Valeriani**  
Former Chief Executive Officer,  
West Health Institute

## Executive Management

**Michael A. Mussallem**  
Chairman & Chief Executive Officer

**Donald E. Bobo, Jr.**  
Corporate Vice President,  
Strategy & Corporate Development

**Todd J. Brinton, M.D., F.A.C.C.**  
Corporate Vice President,  
Advanced Technology  
Chief Scientific Officer

**Daveen Chopra**  
Corporate Vice President,  
Transcatheter Mitral  
& Tricuspid Therapies

**Dirksen J. Lehman**  
Corporate Vice President,  
Public Affairs

**Jean-Luc Lemerrier**  
Corporate Vice President,  
EMEA, Canada, Latin America  
& JAPAC

**Christine Z. McCauley**  
Corporate Vice President,  
Human Resources

**Joseph Nuzzo**  
Corporate Vice President,  
Global Supply Chain & Quality

**Arnold A. Pinkston**  
Corporate Vice President,  
General Counsel

**Gary I. Sorsher**  
Senior Vice President  
Quality & Regulatory Compliance

**Katie M. Szyman**  
Corporate Vice President,  
Critical Care

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

**Larry L. Wood**  
Corporate Vice President &  
Group President, Transcatheter  
Aortic Valve Replacement &  
Surgical Structural Heart

**Bernard J. Zovighian**  
President



FTSE4Good

MEMBER OF  
**Dow Jones  
Sustainability Indices**  
In Collaboration with RobecoSAM

**2022** MSCI ESG Leaders  
Indexes Constituent



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](http://www.newheartvalve.com) or [www.edwards.com](http://www.edwards.com). For the full important safety information, please see [www.ir.edwards.com/annuals-and-proxies](http://www.ir.edwards.com/annuals-and-proxies)

**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.

Edwards EVOQUE Tricuspid Valve Replacement / Edwards Cardioband System / PASCAL 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 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 present 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.

## Trademarks

Edwards, Edwards Lifesciences, the stylized E logo, 1-800-4-A-HEART, Acumen, Acumen IQ, Alterra, Cardioband, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, Edwards SAPIEN M3, Every Heartbeat Matters, EVOQUE, EVOQUE EOS FloTrac, ForeSight, HemoSphere, Hypotension Prediction Index, INSPIRIS, INSPIRIS RESILIA, KONECT, KONECT RESILIA, MITRIS RESILIA, Life is Now, PARTNER, PARTNER 3, PASCAL, PASCAL Ace, RESILIA, SAPIEN, SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN M3 are all trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

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Edwards

# Edwards Lifesciences

2022 Annual Report



Edwards



For Sarah Sue Morbitzer,  
it was always going  
to be “game on!”



Sarah Sue was born with Tetralogy of Fallot, and at four months old underwent open-heart surgery to build the wall between her two ventricles and repair two valves. Being the daughter of a high school volleyball coach, Sarah Sue quickly developed a passion for the sport. She lived just 15 minutes away from the Ohio State University and dreamed of one day becoming a volleyball player for the Buckeyes. In 2020, her dream came true. Upon arriving at campus to begin workouts with her teammates, Sarah Sue noticed she was having trouble catching her breath during conditioning. Knowing her heart history, Sarah Sue's athletic trainer sent her to see a cardiologist at the Ohio

State Richard M. Ross Heart Hospital. The cardiologist said she could continue conditioning and practice, but she might need to adjust her workouts and give herself more time for recovery. Not wanting to sit out or slow down, Sarah Sue decided to get her valve replaced over the winter holidays. In December of 2020, she received the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive PreStent. To honor her new valve, Sarah Sue proudly named it Valerie. Just one month later, she played in her first volleyball match wearing scarlet and grey. After two successful seasons, Sarah Sue earned an athletic scholarship at Ohio State.

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*“I always stepped on the court with a lot of heart and passion,  
but after I got my valve, it meant even more.”*

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# A Letter to Our Shareholders

Leading Edwards Lifesciences has been the greatest privilege of my life.

As I look back on the past two decades, I reflect on many of Edwards' extraordinary accomplishments – the development of our life-saving innovations, the strong patient-focused culture we live every day,



and most importantly, the impact we have had on so many patients around the world. I am proud of our talented and dedicated leadership team and our employees who have made all this possible.

The day Edwards became an independent company on April 3, 2000, was exciting, but our future was still uncharted. We were in the very early stages of creating our company and the technologies that would go on to change the lives of so many. Now, 23 years later, I am confident as ever that our future is extremely bright.

While the company and our world have grown and changed since that first day at Edwards, we have never lost sight of why we are here. True to our Credo, which concludes with, “Helping patients is our life’s work, and life is now,” we have stayed focused on our long-term, strategic goals and fostered a patient-focused culture that drives all we do. Impressively, our most recent internal survey found that 93% of our employees consider what is important to patients when making decisions.



### Innovation

Pioneer breakthrough technologies with compelling evidence



### Leadership

Lead groundbreaking standards of care through trusted relationships



### Focus

Singular focus on the large unmet needs of structural heart and critically ill patients

We have continued to partner with clinicians, regulators, hospitals and health systems to bring lifesaving therapies to patients around the world. For example, we have been involved in more than 800,000 transcatheter aortic valve replacement (TAVR) procedures since we pioneered the technology more than a decade ago. We have stayed true to our innovation strategy, even during the pandemic, and have strategically invested in research and development. Our global supply chain has proven resilient, enabling us to meet physician and patient needs. We have also continued to grow our talented and dedicated employees – now stronger than 17,000 worldwide, including more than 2,000 engineers.

It is gratifying to reflect on all we have achieved together, but I also know Edwards is just getting started. We have a leadership team with unmatched experience who shares my commitment to patients. We have worked cohesively for many years, collaborating on Edwards’ strategy, and I am certain the company will continue to build on our legacy of patient impact, innovation and growth.

It is this confidence that underpins my decision to retire in May of this year and step into a different role at Edwards. I feel proud of the planful transition that the Board and I have mapped out. I know that my successor, Bernard Zovighian, is as right for this new role as he was to lead our successful Transcatheter Mitral and Tricuspid Therapies (TMTT) business and, before that, Surgical Structural Heart (where it all began for Edwards). He cares deeply about patients, our employees and our company. He brings to the job a strong strategic mindset, deep experience in innovation and passion for establishing trusted partnerships.

### Culture and Strategy Led

The strong culture and patient-focused strategy we have at Edwards requires establishing critical partnerships based on mutual trust. It requires an

emphasis on quality, integrity and transparency. It requires talented employees who are committed to patients, who think creatively and who are dedicated to lifelong learning. This in turn requires a workplace where our employees feel they belong, where they enjoy and value their work, and where they can be their best.

Through the commitment to our strategy, we are continuing to generate high-quality scientific evidence to demonstrate that our life-saving technologies lead to substantial health and economic benefits.

### Innovation Prioritized

Our leading therapies continue to transform patient care around the world. To help more patients and further strengthen our long-term leadership position, we continue to invest in research and development at a significant rate of 17-18% of sales.

While many companies in our industry try to grow through diversification and acquisitions, we have stayed committed to organic growth through innovation in structural heart and critical care.

We have considerable research underway to demonstrate the value of our innovative technologies and hopefully expand the number and type of patients who benefit from those technologies. As an example, under current rules, most people receive treatment when they are diagnosed with a disease, but many patients with heart valve failure are not eligible to receive treatment until they display symptoms. Our pivotal trial, EARLY TAVR, is studying the treatment of severe aortic stenosis (AS) patients before debilitating symptoms appear and may help us to determine if there are dangers associated with waiting to treat these patients. In addition, enrollment is continuing in PROGRESS, a pivotal trial studying the treatment of patients with moderate AS.

The global TAVR market will continue to be driven by greater awareness and advances in new technologies, as well as indication expansions and increased global adoption. We expect to help twice as many TAVR patients by 2028.



In the face of systemic tensions that delay or deny treatment to older patients alongside hospital staffing challenges and patients reluctant to seek care, we have also taken on several initiatives to ensure that heart patients get the care they need. And we are encouraged by how organizations like the American Heart Association are engaging to help improve the quality of care delivery for patients who need it.

In TMTT, we are transforming treatment for patients with severe mitral and tricuspid valve disease. To do this, we need differentiated therapies, positive clinical trial results to support approvals and adoption, and a strong partnership with clinicians to produce real-world clinical outcomes.

Clinical experience with our therapies is showing important progress in addressing the unmet needs of these patients. We recently shared positive results from the TRISCEND study of our EVOQUE transcatheter tricuspid valve replacement system. We aim to achieve approvals for the EVOQUE system in Europe this year and in the U.S. by the end of 2024. We are pleased to see continued adoption of the PASCAL repair system in Europe and the U.S. with more than 10,000 patients who have now been treated with PASCAL.

In our Surgical business, we are advancing our leadership by identifying and solving critical unmet patient needs in cardiac surgery. In 2022, we received FDA approval to introduce our MITRIS RESILIA valve. We will also continue to broaden the adoption of our flagship surgical aortic heart valve, INSPIRIS RESILIA, which is changing the standard of tissue durability in cardiac surgery.

In Critical Care, we have improved the quality of care for more than 16 million patients by creating new technologies, expanding clinical evidence and driving adoption. We continue to evolve our hemodynamic monitoring platform, which uses machine learning to help clinicians predict and prevent hypotension. We recently introduced connectivity to this monitoring platform to allow clinicians to access their patients' continuous blood pressure data on their smartphones.

We believe our opportunity to serve structural heart and critical care patients will nearly double to \$20 billion by 2028.

## Committed Corporate Citizens

The Edwards Lifesciences Foundation has focused on supporting programs designed to treat underserved people to reduce heart valve disease, to strengthen the communities where Edwards' employees live and work

and to promote employee volunteerism. We also aspire to have all our employees engage in charitable efforts that are meaningful to them, and I am proud to share that the great majority did so in 2022. Our signature initiative, *Every Heartbeat Matters*, is focused on improving the lives of an additional 2.5 million underserved structural heart and critical care patients by the end of 2025.

Sustainability, ethical behavior, supporting community health, and fair and inclusive practices are part of everything we do at Edwards. Our commitment to environmental, social and governance (ESG) practices continue to lead to numerous awards and recognitions, including the Dow Jones Sustainability World Index for the third year in a row. While we are honored to receive accolades, this is not the reason we embrace ESG practices. We do so because it's core to our credo and behaving as a trusted partner is part of our values.

## Strong Global Performance During a Challenging 2022

Though 2022 was still a challenging year for hospitals and health systems – which had an impact on our business – the lingering effects of the pandemic are dissipating, as hospitals rebuild staffing capacity, and more heart patients seek care. We have also partnered with clinicians and hospitals to optimize TAVR programs, leading to significant reductions in the length of procedures and hospital stays, as well as the number of staff needed for the procedure.

In 2022, our company grew eight percent on a constant currency basis versus 2021. Our 2022 adjusted earnings per share grew 12 percent. Our results fell short of our expectations and were primarily impacted by hospital staffing shortages around the globe, and foreign currency rates that moved significantly during the year.

We received regulatory approvals to introduce our industry-leading SAPIEN 3 Ultra RESILIA valve in the U.S., Japan and other key geographies around the world, and we are proud we have seen strong adoption of this valve in both countries. RESILIA tissue now serves as the platform for Edwards' new class of valves. A recent study showed positive results for RESILIA tissue at five years and provides the potential to extend the durability of all of our valves.

Our next generation PASCAL Precision mitral repair system received approval in Europe and early approval in the U.S. to treat patients suffering from degenerative mitral regurgitation.

Our innovative therapies and development will continue to drive strong organic growth in the years to come, as will our initiatives to improve patient access to life-saving care.

## Looking to the Future

I feel strongly that Edwards' best days are ahead, and the company will thrive and grow with Bernard as CEO. Aside from his already impressive skills and decades of medtech experience, including eight years here at Edwards, he will be supported by our expert, highly engaged board of directors, as well as our stellar executive team. At the annual meeting in May, I will

stand for election as non-executive chairman of Edwards' Board, and I look forward to my continued engagement in this role.

To our employees, I want to thank you, again, for everything that you do for our company and for patients around the world. It has truly been my greatest honor to be Edwards' CEO and I look forward to supporting Edwards for years to come.

Sincerely,



**Michael A. Mussallem**

Chairman & Chief Executive Officer



## More About Bernard

Bernard J. Zovighian is president of Edwards Lifesciences, and will become CEO of the company in May 2023. In his time as president, he is working closely alongside Mike Mussallem in engagement with Edwards' board of directors, executive leadership team, worldwide employees and other

stakeholders to further Edwards' patient-focused innovation strategy. Prior to this leadership transition, Zovighian served since January 2018 as corporate vice president responsible for the company's Transcatheter Mitral and Tricuspid Therapies (TMTT) business. As the leader for TMTT, Zovighian established a global

organization focused on developing and delivering a portfolio of therapies designed to change the standard of care for mitral and tricuspid patients. Zovighian joined Edwards Lifesciences in January 2015 as vice president and general manager of the Surgical Structural Heart business, later serving as corporate vice president of the surgical business from 2016 until he began leading TMTT. Prior to joining Edwards, Zovighian held a variety of roles with increasing levels of responsibility at Johnson & Johnson (J&J) for nearly 20 years, in roles such as regional leadership outside of the United States and worldwide president of one of the company's divisions. He has dual master's degrees in science and business from Universities of Marseille, France.

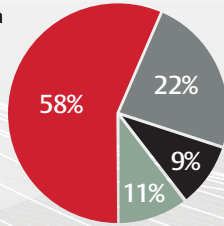
This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. Statements 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 2023 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. These risks and uncertainties include, but are not limited to: our success in developing new products and avoiding manufacturing and quality issues; clinical trial or commercial results or new product approvals and therapy adoption; the impact of public health crises, including the COVID-19 pandemic; the impact of domestic and global economic conditions; competitive dynamics in the markets in which we operate; our reliance on vendors, suppliers, and other third parties; damage, failure, or interruption of our information technology systems; consolidation in the healthcare industry; our ability to protect our intellectual property; our compliance with applicable regulations; our exposure to product liability claims; use of our products in unapproved circumstances; changes to reimbursement for our products; the impact of currency exchange rates; unanticipated actions by the United States Food and Drug Administration and other regulatory agencies; changes to tax laws; unexpected impacts or expenses of litigation or internal or government investigations; and other risks detailed under "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.

Caution: In the U.S., EVOQUE and SAPIEN M3 are investigational devices and are not commercially available.

# 2022 Highlights

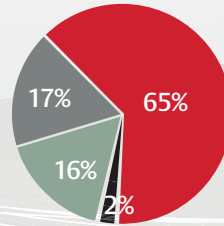
2022 Sales by Geographic Region

- United States
- Europe
- Japan
- Rest of World

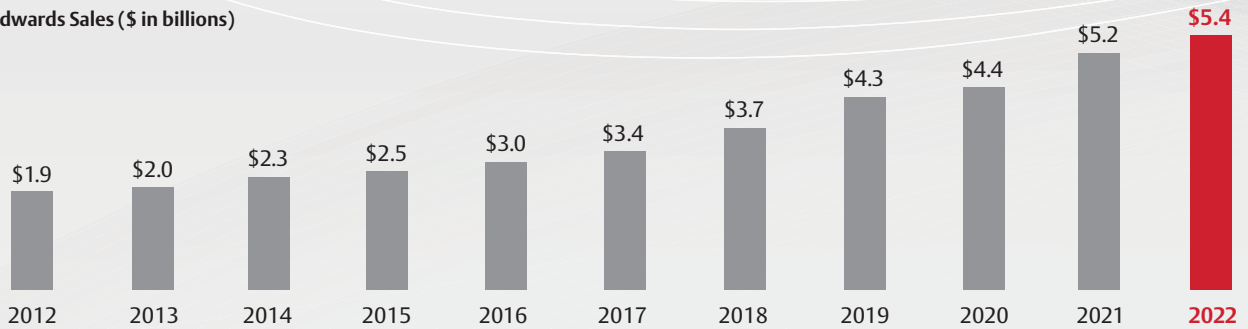


2022 Sales by Product Line

- TAVR
- Surgical
- Critical Care
- TMTT



Edwards Sales (\$ in billions)



**800K+** patients treated with transcatheter technologies

**2,000+** engineers

**17,000+** global employees

**8%** underlying sales growth

**12%** adjusted EPS growth



## Transcatheter Aortic Valve Replacement

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 an approved treatment option for all Severe Symptomatic Aortic Stenosis patients including those at low risk to surgery in Europe, the US, Japan and other countries around the world based on the superiority of outcomes demonstrated in the PARTNER 3 Trial. Building on the benefits of the SAPIEN 3 platform, the SAPIEN 3 Ultra valve with RESILIA tissue technology is now available in the US and Japan.



**Edwards SAPIEN 3 Ultra RESILIA** transcatheter heart valve

The Edwards SAPIEN 3 Ultra transcatheter heart valve system with RESILIA tissue is built upon the proven SAPIEN platform featuring the same tissue technology used in the leading surgical valve in the US, a ~40 percent taller\*, textured outer skirt designed to further reduce paravalvular leak.

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.

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



**Alterra** adaptive prenent and **SAPIEN 3** transcatheter heart valve



**Edwards SAPIEN 3 Ultra** transcatheter heart valve and delivery system

\* Compared to the Edwards SAPIEN 3 valve.

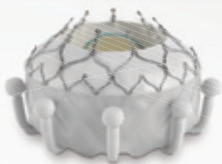
## Transcatheter Mitral & Tricuspid Therapies

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



**Edwards PASCAL** repair system

Our PASCAL repair platform delivers differentiated transcatheter leaflet repair for patients with mitral and tricuspid regurgitation. Through continuous innovation coupled with our high touch procedural and imaging support, the PASCAL system enables our physician partners to optimize clinical outcomes for their patients.



**Edwards EVOQUE\*** tricuspid replacement system

The EVOQUE tricuspid replacement system expands our treatment options for patients with tricuspid valve disease, providing a new transcatheter therapy for patients with limited options today. SAPIEN M3 and EVOQUE Eos mitral valve replacement systems are designed to treat patients with mitral valve disease. We are advancing our clinical experience with these mitral and tricuspid replacement therapies through continued enrollment in pivotal trials and clinical studies.

\* Investigational device. Limited to investigational use only.



**Edwards Cardioband\*\*** tricuspid reconstruction system

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

\*\* CE Mark in EU. Investigational device and not available for sale in the US.

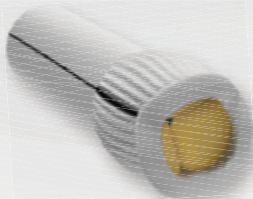
## Surgical Structural Heart

Edwards Lifesciences has a proven commitment to ongoing innovation in surgical structural heart solutions, to advance the state of the art and put better outcomes within reach. Today's RESILIA tissue portfolio represents the best of creative scientific minds coming together to address the unmet needs and satisfy patient demands for better surgical options.



**INSPIRIS RESILIA**  
aortic valve

The market-leading 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. Unlike other valves, the INSPIRIS valve is specifically designed to deliver a controlled and predictable expansion during valve-in-valve deployment, providing a patient lifetime management solution for the surgeon.



**KONECT RESILIA**  
aortic valved conduit

KONECT RESILIA aortic valved conduit is 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.



**MITRIS RESILIA**  
mitral valve

The MITRIS RESILIA mitral valve is built on the trusted Carpentier-Edwards PERIMOUNT valve platform with RESILIA tissue and an enhanced delivery experience. Cobalt chromium bands

provide good visibility under fluoroscopy for easy identification of the landing zone for potential future transcatheter interventions.

This valve handles the pressure of the mitral position and allows patients to live without the quality-of-life compromises required with mechanical valves.

## Critical Care

Edwards is the leader in smart hemodynamic monitoring solutions including monitoring platforms, predictive software, and sensors ranging from invasive to noninvasive, all of which play an important role in patient recovery. This portfolio of advanced hemodynamic solutions helps clinicians make proactive decisions for individualized patient care. All monitoring solutions are offered on our HemoSphere monitor, which brings pressure, flow, and tissue oximetry to a single screen.



**HemoSphere** advanced monitoring platform with HPI software

Acumen Hypotension Prediction Index software is a first-of-its-kind predictive software developed with machine learning. It detects hemodynamic instability and hypotension up to 15 minutes before it occurs and enables clinicians to prevent or treat hypotension. Hypotension is associated with post-operative complications including acute kidney injury and myocardial injury.

Acumen Assisted Fluid Management software is our second software developed with machine learning. This software predicts if a patient is fluid responsive, and is designed to help keep patients in the optimal fluid range.

Our latest Smart Recovery solutions, such as Acumen IQ sensor and Acumen IQ noninvasive finger cuff, unlocks our predictive software and provide clinicians advanced hemodynamic

parameters and decision support to help them stay ahead of their patient's rapidly evolving status.



**ForeSight Elite**  
tissue oximetry sensor

Our ForeSight tissue oximetry sensor helps clinicians monitor for low oxygen levels in the brain or tissue, which can cause significant complications if left untreated. With the edition of ForeSight sensor to our HemoSphere monitor, Edwards became the first to offer clinicians the ability to monitor the heart and the brain from one screen.

**Acumen IQ**  
finger cuff

**Acumen IQ**  
sensor



## Our Aspirations – The Heartbeat of Edwards

At Edwards, our Credo defines our culture, strategic priorities, and our vision for sustainability and long-term value creation. Our environmental, social and governance (ESG) or sustainability goals are closely aligned with our corporate aspirations and are intended to address those topics that have been assessed to be of the most importance to Edwards and its stakeholders.

### Transforming patient lives with breakthrough medical technologies



Edwards is driven by a passion to help patients, partnering with clinicians to develop innovative technologies in the areas of structural heart disease and critical care monitoring. We put patients first, working to produce better technologies that enable better outcomes for patients.

### Excelling as a trusted partner through distinguished quality and integrity



Edwards conducts business ethically and with integrity, providing the highest level of care and respect for our partners. We are committed to the quality and safety of our products, driving innovation and promoting resource efficiency.

### Fostering an inclusive culture where all employees grow and thrive



Fulfilling our mission to help patients requires a strong, healthy and talented workforce. Edwards recruits top candidates, offers employee wellness and engagement programs and fosters a diverse and inclusive culture to help employees deliver their best.

### Passionate engagement that strengthens our communities



Edwards is committed to strengthening the health of our global communities. With patients as our top priority, we work to increase access to our innovative therapies, improve efficiency of healthcare processes, improve awareness of and treatment for life-threatening diseases and provide opportunities for our employees to give back.

### Delivering exceptional shareholder value



Through all of our sustainability initiatives and delivering on our focused company strategy, Edwards is positioned for long-term profitability that will benefit our stakeholders and also our bottom line.





**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.



## 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*

## 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 and sales growth information, which excludes currency exchange rate fluctuations, the conversion to a consignment inventory system for surgical structural heart (“Surgical”), and the positive impact of transcatheter aortic valve replacement (“TAVR”) stocking sales in Germany and the negative impact of de-stocking. The Company uses the term “adjusted” to also exclude intellectual property litigation expenses, fair value adjustments to contingent consideration liabilities arising from acquisitions, amortization of intangible assets, a significant program discontinuation, significant charges associated with TAVR inventory write offs, the conversion to a consignment inventory for Surgical, the positive impact of TAVR stocking sales in Germany and the negative impact of de-stocking, impairment of long-lived assets, pension curtailment gains, 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 currency 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)	2022	2021	2020	2019	2018
<b>GAAP Net Sales</b>	<b>\$5,382.4</b>	\$5,232.5	\$4,386.3	\$4,348.0	\$3,722.8
Impact of Surgical consignment	–	–	–	–	82.5
Impact of Germany stocking	–	–	–	–	8.0
<b>Adjusted Net Sales</b>	<b>\$5,382.4</b>	\$5,232.5	\$4,386.3	\$4,348.0	\$3,813.3

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)	2022	2021	2020	2019	2018
<b>GAAP Net Income</b>	<b>\$1,521.9</b>	\$1,503.1	\$823.4	\$1,046.9	\$722.2
Non-GAAP adjustments:					
Intellectual property litigation expenses, net	11.9	15.5	28.5	25.2	26.4
Change in fair value of contingent consideration liabilities, net	(35.0)	(121.6)	12.3	(7.1)	(8.0)
Amortization of intangible assets	4.8	6.9	4.6	4.0	2.4
Program discontinuation	47.0	–	–	–	–
Litigation settlement	–	–	305.1	–	137.5
TAVR inventory write off	–	–	–	55.2	–
Surgical consignment conversion	–	–	–	–	54.7
TAVR Germany stocking sales	–	–	–	–	4.7
Impairment of long-lived assets	–	–	–	40.6	109.3
Pension curtailment gain	–	–	–	–	(6.3)
Purchased in-process research and development	–	–	–	18.1	–
Impact from U.S. tax legislation	–	–	–	–	(2.5)
Tax audit settlements	–	–	–	–	(36.1)
<b>Adjusted Net Income</b>	<b>\$1,550.6</b>	\$1,403.9	\$1,173.9	\$1,182.9	\$1,004.3

## Reconciliation of GAAP to Adjusted Diluted Earnings Per Share

<b>GAAP Diluted Earnings Per Share</b>	<b>\$2.44</b>	\$2.38	\$1.30	\$1.64	\$1.13
Non-GAAP adjustments:					
Intellectual property litigation expenses, net	0.03	0.02	0.05	0.04	0.04
Change in fair value of contingent consideration liabilities	(0.06)	(0.19)	0.02	(0.01)	(0.01)
Amortization of intellectual property	–	0.01	0.01	0.01	–
Program discontinuation	0.07	–	–	–	–
Litigation settlement	–	–	0.48	–	0.21
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
Pension curtailment gain	–	–	–	–	(0.01)
Purchased in-process research and development	–	–	–	0.03	–
Tax audit settlements	–	–	–	–	(0.06)
<b>Adjusted Diluted Earnings Per Share</b>	<b>\$2.48</b>	\$2.22	\$1.86	\$1.86	\$1.57

## Adjusted Free Cash Flow

Twelve months ended December 31 (in millions)	2022	2021	2020	2019	2018
Net cash provided by operating activities	\$1,218.2	\$1,732.1	\$1,054.3	\$1,182.9	\$926.7
Capital expenditures	(244.6)	(325.8)	(407.0)	(254.4)	(238.7)
Litigation settlements	–	–	86.4	138.3	–
Tax audit settlement	–	–	–	–	56.7
Repatriation tax payments	–	–	–	–	41.0
<b>Adjusted Free Cash Flow</b>	<b>\$973.6</b>	\$1,406.3	\$733.7	\$1,066.8	\$785.7

## Adjusted Net Sales Growth

Twelve months ended December 31	2022	2021	2020	2019	2018
<b>GAAP Net Sales Growth Rate</b>	<b>2.9%</b>	19.3%	0.9%	16.8%	8.4%
Impact of Surgical consignment	0.0%	0.0%	0.0%	(2.5%)	2.4%
Impact of Germany stocking	0.0%	0.0%	0.0%	(0.3%)	0.3%
Impact of CASMED acquisition	0.0%	0.0%	0.0%	(0.5%)	0.0%
Impact of foreign exchange	4.8%	(1.5%)	(0.3%)	1.8%	(1.1%)
<b>Adjusted Net Sales Growth Rate</b>	<b>7.7%</b>	17.8%	0.6%	15.3%	10.0%

Note: Numbers may not calculate due to rounding.



**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, 2022

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:

<u>Title of each class</u>	<u>Trading Symbols(s)</u>	<u>Name of each exchange on which registered:</u>
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 .

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recover analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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, 2022 (the last trading day of the registrant's most recently completed second quarter): \$58,453,646,002 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, 2023, was 608,313,396.

**Documents Incorporated by Reference**

Portions of the registrant's proxy statement for the 2023 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2022) are incorporated by reference into Part III, as indicated herein.

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**EDWARDS LIFESCIENCES CORPORATION**  
**Form 10-K Annual Report—2022**  
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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. Statements other than statements of historical or current 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, the expected impact of macroeconomic conditions on our business, any predictions, opinions, expectations, plans, strategies, objectives and any statements of assumptions underlying any of the foregoing relating to the our 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: our success in developing new products and avoiding manufacturing and quality issues; clinical trial or commercial results or new product approvals and therapy adoption; the impact of public health crises, including the COVID-19 pandemic; the impact of domestic and global economic conditions; competitive dynamics in the markets in which we operate; our reliance on vendors, suppliers, and other third parties; damage, failure, or interruption of our information technology systems; consolidation in the healthcare industry; our ability to protect our intellectual property; our compliance with applicable regulations; our exposure to product liability claims; use of our products in unapproved circumstances; changes to reimbursement for our products; the impact of currency exchange rates; unanticipated actions by the United States Food and Drug Administration and other regulatory agencies; changes to tax laws; unexpected impacts or expenses of litigation or internal or government investigations; 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 United States 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.

### WEBSITE REFERENCES

In this Annual Report on Form 10-K, we make references to our website at [www.edwards.com](http://www.edwards.com). References to our website through this Form 10-K are provided for convenience only and the content of our website does not constitute a part of, and shall not be deemed incorporated by reference into, this Annual Report on Form 10-K.

## **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 our field 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 cardiac surgeon 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 (typically an interventional cardiologist) 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**

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](http://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 aortic heart valves. The *Edwards SAPIEN* family of valves, including *Edwards SAPIEN XT*, the *Edwards SAPIEN 3*, the *Edwards SAPIEN 3 Ultra*, and the *Edwards SAPIEN 3 Ultra RESILIA* transcatheter 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 aortic 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% of our net sales in each of 2022, 2021, and 2020, respectively.

### ***Transcatheter Mitral and Tricuspid Therapies***

We continue to make 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 development and clinical phases, the *PASCAL PRECISION* and *Cardioband* transcatheter valve repair systems are commercially available in Europe for mitral and tricuspid valve repair. As of 2022, the *PASCAL PRECISION* system is also commercially available in the U.S. for degenerative mitral regurgitation patients. The *PASCAL PRECISION* system addresses the needs of patients with mitral or tricuspid regurgitation through leaflet approximation, while the *Cardioband* system enables clinicians to reduce the valve’s annulus and lower regurgitation. In addition to transcatheter repair, we believe transcatheter replacement is key to unlocking the full mitral and tricuspid opportunity. We believe our two-platform mitral replacement strategy positions us for leadership in the mid-to-long term. *SAPIEN M3* is based on the proven *SAPIEN* valve while *EVOQUE Eos* is designed specifically for mitral patients. For tricuspid valve replacement, our *EVOQUE* system is also sub 30-French, and available in a variety of valve sizes to enable treatment in a wide range of patient anatomies.

### ***Surgical Structural Heart***

We are innovating in the field of cardiac surgical therapies to improve the quality of life for patients. Our *RESILIA* tissue, with published clinical data showing 0% structural valve deterioration through five years<sup>1</sup>, is helping us redefine tissue durability standards. Our latest innovation, the *INSPIRIS RESILIA* aortic valve, is built on our *PERIMOUNT* platform, offering *RESILIA* tissue and *VFit* technology. *INSPIRIS* is the leading aortic surgical valve in the world. Sales of our surgical therapies in the United States also continue to gain traction with *KONECT RESILIA*, the first pre-assembled, aortic tissue valved conduit.

The *MITRIS RESILIA* valve, our newest mitral valve incorporating our latest tissue technology, is now commercially available in both the U.S. and Japan. We believe the demand for surgical structural heart therapies is growing worldwide, and that our innovation strategy will continue to strengthen our leadership and positive impact on patients.

<sup>1</sup> Bavaria, et al. Five-year Outcomes of the COMMENCE trial investigating Aortic Valve Replacement with a Bioprosthetic Valve with a Novel Tissue. The Society of Thoracic Surgeons 2021 Annual Meeting; Bartus, et al. Final 5-year outcomes following aortic valve replacement with *RESILIA* tissue bio prosthesis. European Journal of Cardio-Thoracic Surgery, 2020.



Sales of our surgical tissue heart valve products represented 15%, 15%, and 16% of our net sales in 2022, 2021, and 2020, respectively.

### **Critical Care**

We are the world leader in advanced hemodynamic monitoring systems used to measure a patient's heart function and fluid status in surgical and intensive care settings. Edwards' complete hemodynamic portfolio helps clinicians make proactive clinical decisions that can improve patient recovery. The portfolio includes the minimally-invasive *FloTrac* and *Acumen IQ* sensors, the noninvasive *ClearSight* and *Acumen IQ* cuffs, and the *ForeSight* noninvasive tissue oximetry sensor. We also support clinical needs with our well-established *Swan-Ganz* pulmonary artery catheters and arterial pressure monitoring products. Compatible with our portfolio of sensors and catheters, the *HemoSphere* monitoring platform displays valuable physiological information. Our first predictive algorithm, *Acumen Hypotension Prediction Index* software, alerts clinicians in advance of a patient developing dangerously low blood pressure. Our latest algorithm, *Acumen Assisted Fluid Management* software, provides patient-specific fluid suggestions to help keep patients in an optimal range during surgery.

### **Competition**

The medical technology industry is highly competitive. We compete with divisions of larger companies as well as smaller companies that offer competitive product lines in certain geographies in which we operate. We also compete with both established and newer technologies that target the patients served by our products. 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 believe we hold leadership positions because we develop and produce safe and effective therapies supported by rigorous clinical studies with extensive data and with 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 Artivion, Inc (formerly 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, a subsidiary of Masimo Corporation.

### **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 2022.

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 2022, 58% of our net sales were derived from sales to customers in the United States.

**Outside of the United States.** In 2022, 42% of our net sales were derived outside of the United States through our direct sales forces and independent distributors. Of the total sales outside of the United States, 52% were in Europe, 21% were in Japan, and 27% were in Rest of World. We sell our products in approximately 100 countries, including Japan, Germany, France, United Kingdom, Italy, China, and Canada. A majority of the sales and marketing approach outside of 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 the Dominican Republic and Puerto Rico.

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 quality products to our patients 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 uses 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 2022, 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 5% year over year, representing 18% of 2022 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. 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.

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 United States and in foreign countries. We continue to innovate and file new patent applications to protect our new products and technologies.

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

### **Government Regulation and Other Matters**

Our products and facilities are subject to regulation by numerous government agencies, including the FDA, European 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, including, but not limited to, those regulating employee health and safety, labor, competition, trade secret, 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.

***Regulation Outside of the United States.*** Outside of the United States, the regulation of medical devices is complex. In Europe, our products are subject to extensive regulatory requirements. The regulatory regime in the European Union (“EU”) 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 EU’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 EU 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 EU implemented a new regulatory scheme for medical devices under the Medical Device Regulation (“MDR”). The MDR became effective on May 26, 2021 and brought 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”). 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***

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 routinely engages with leadership to review and discuss our human capital management (“HCM”), with time dedicated at each regularly scheduled meeting to discuss talent management, which include topics such as talent strategy, diversity, succession planning, employee development, employee health, safety, and welfare, results of employee surveys, and compensation. Our Board of Directors also annually approves the strategic talent imperatives that are tied to our Key Operating Drivers (“KODs”). Our KODs are tracked using a point system across our entire organization that focus the Company and management toward short-, medium-, and long-term goals. The strategic talent imperatives are developed to identify talent related initiatives that support achievement of the KODs.

In addition, the Chief Executive Officer (“CEO”) and his leadership team have talent management related performance goals tied to their compensation; these Performance Management Objectives are reviewed on an annual basis, tracked, and then reported to and evaluated by our Board of Directors.

As we scale to reach more patients around the world, we have integrated our Talent & Organization (“T&O”) Strategy with our Edwards Strategic Planning process. The purpose of our T&O Strategy is to anticipate dynamic global trends related to our workforce, develop our talent to meet future organizational needs, and enable us to be well-poised to meet these needs. Our T&O Strategy enables us to explore external workforce signals, share insights, and identify and build emerging capabilities across our organization. This has enabled us to build a comprehensive succession planning process that allows us to build strong talent from within while we pursue an aggressive recruiting process to fill any gaps with highly qualified external talent. This consistent and scalable approach looks across all our product groups, regions, and significant functions to align and elevate priorities, critical capabilities, and organizational evolutions in line with our strategic plan. This integrated approach informs our yearly objectives and fuels our talent roadmap across the strategic horizon.

Our HCM governance includes a global talent development review (“TDR”) process 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. We track our performance regularly.

### ***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 an ethical culture where we celebrate diversity, promote good health and safety, empower employees to speak up, and ensure that employees’ voices are heard. We strive to offer competitive employee well-being 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.

### ***Diversity, Inclusion, and Belonging***

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 have established a Diversity, Inclusion, and Belonging strategy that includes our four focus areas of Business, People, Communication, and Community, and whose overriding priority is “The Patient.” As a practice, all employees receive unconscious bias training as a foundational aspect of our culture.

### ***Employee Listening***

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 gain employees' feedback in a confidential manner. The CEO and Executive Leadership Team hold themselves accountable to act on the results of the survey, and these results are reviewed by management with our Board of Directors. This initiative helps us gain insights on various topics including patient focus, diversity, inclusion and belonging, quality, innovation, engagement, as well as a sense of support at all levels of the organization. Speak-Up is a resource available to all employees to bring forth compliance related concerns; a key element of our compliance program is that each employee is accountable for maintaining ethical business practices. In addition, during each quarterly townhall meeting, our CEO 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.

### ***Total Well-being***

We understand that good health leads to better performance. We offer competitive employee well-being packages that include, among other things, health and wellness insurance, health savings accounts, family support services, and a variety of site-specific programs. We regularly evaluate our well-being package to make modifications that are aligned with the competitive landscape, legislative changes, and the unique needs of our population. We also provide robust well-being programs that address prevention, nutrition, mental health, physical activity, financial fitness, and community service. In recent years, mental well-being has become a central topic for organizations worldwide. As part of our regular evaluation and commitment to putting employees first, we launched a new program, Mind+, which offers a wide variety of mental well-being programs for our employees. This commitment extends to creating a work environment where employees can feel confident speaking about mental well-being with their managers and know how best to access the tools and resources available to support them. We believe there are strong benefits when employees are feeling their best. Employees who are mentally healthy are more innovative, resilient, better decision-makers, and able to build stronger relationships. We also believe that prioritizing and promoting Mind+ allows us to help patients around the world to live longer, healthier, and more productive lives and supports employees to be their best self at home and at work.

### ***Talent Development***

Edwards has established a long-term aspiration to grow and develop talent significantly, centering our efforts around critical leadership and technical skills for the present and future needs of the business. Our learning and development structure and processes strive to meet the internal demand to develop our talent in such a way that demonstrates impact at scale and delivered to our workforce through optimized learning modalities. This includes leadership training programs, including our ethical decision making training program for managers.

### ***Headcount and Labor Representation***

As of December 31, 2022, we had approximately 17,300 employees worldwide, the majority of whom were located in the United States, Singapore, the Dominican Republic, and Costa Rica. 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](http://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. Please note that the headers and summary provided below are only intended to assist the reader in navigating the risk factors; some risks, present or future, may implicate multiple types of risks. Please read all risk factors in their entirety.*

### **Summary of Risk Factors**

We group our risk factors into three principal sections: (1) Business and Operating Risks; (2) Market and Other External Risks and (3) Legal, Compliance and Regulatory Risks. The following summarizes the principal risks and uncertainties affecting our business, financial condition, and results of operations. This summary should not be relied upon as an exhaustive summary of the material risks facing our business and you should read this summary together with the more detailed description of risks and uncertainties discussed below.

#### **Business and Operating Risks**

- Failure to successfully innovate and market products
- Unsuccessful clinical trials or procedures
- Manufacturing, logistics, or quality problems
- Public health crises, including pandemics and epidemics
- Competition
- Dependence on key physicians and research institutions
- Reliance on vendors, suppliers, and other third parties
- Damage, failure, or interruption of our information technology systems, including due to cyber-based attacks and breaches
- Failure to recruit and retain qualified talent or execute management succession plans
- Underperforming operations or unsuccessful business acquisitions or strategic alliances

#### **Market and Other External Risks**

- Risks associated with international sales and operations
- Inability to obtain government reimbursement or reductions in reimbursement levels
- Industry consolidation

#### **Legal, Compliance and Regulatory Risks**

- Inability to protect our intellectual property
- Inability to defend against intellectual property claims from third parties
- Compliance with government regulations



- Losses from product liability claims
- Use of products in unapproved circumstances
- Substantial costs from environmental, health and safety regulations
- Climate change
- Regulatory actions relating to animal borne illnesses

**Business and Operating Risks**

***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 because of the introduction of a competitor's newer technologies or changing customer preferences. 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 successfully market them could be constrained by a number of different factors, including competitive products and pricing, 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, and any such delay, suspension, or termination could have a material adverse effect on our prospects or the market's view of our future prospects.

***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, cyber incidents, 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 partners 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 are subject to risks associated with public health crises, including the COVID-19 pandemic and other pandemics or epidemics.***

We are subject to risks associated with public health crises, including the global health concerns related to the COVID-19 pandemic. The 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 operations and the operations of our customers, suppliers, and business partners. Other public health crises, including any future epidemics or pandemics, could result in similar adverse impacts on our business and markets. Financial or operational impacts that we have experienced in connection with the COVID-19 pandemic and may experience as a result of future COVID-19 outbreaks or other public health crises include:

- Staffing shortages at hospitals which can add to the barriers along the patient treatment pathway;
- Impacts and delays to clinical trials, our pipeline milestones, or regulatory clearances and approvals;
- 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; or
- Significant volatility or reductions in demand for our products.

Depending on the severity of the financial and operational impacts, our business, financial condition, and results of operations may be materially adversely impacted. The extent to which the COVID-19 pandemic or other future public health crises may impact our business, results of operations, and financial condition depends on many factors which are highly uncertain and are difficult to predict. These factors include, but are not limited to, the duration and spread of any outbreak, its severity, the actions to contain or address the impact of the outbreak, the timing, distribution, and efficacy of vaccines and other treatments, United States and foreign government actions to respond to possible reductions in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume.

***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 technologies of many types and 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.

***The success of many of our products depends upon certain key physicians and research institutions.***

We work with leading global physicians and research institutions who 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 with the research institutions of which they are a part or to continue to receive their advice and input or we are otherwise unsuccessful in maintaining strong working relationships with these physicians or their research institutions, 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.

***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 experience from time to time, and may continue to 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 or supply medical technology companies, including due to the burdens of applicable quality requirements and regulations or for no reason at all;
- The limitation or ban of certain chemicals or other materials used in the manufacture of our products; and
- Delays or shortages due to trade or regulatory embargoes.

Additionally, any significant increases in the cost of raw materials, whether due to inflationary pressure, supply constraints, regulatory changes, or otherwise, could adversely impact our operating results. 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 or at all, which could have a material adverse effect on our business.

***Failure to protect our information technology infrastructure and our products 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, and data corruption.

In addition, our information technology infrastructure and products are vulnerable to cyber-based attacks. Cyber-based attacks can include, but are not limited to, computer viruses, denial-of-service attacks, phishing attacks, ransomware attacks, and other introduction of malware to computers and networks; unauthorized access through the use of compromised credentials; exploitation of design flaws, bugs, or security vulnerabilities; intentional or unintentional acts by employees or other insiders with access privileges; and intentional acts of vandalism by third parties and sabotage. In addition, United States federal and state laws and regulations, and the laws and regulations of jurisdictions outside of the United States, such as the General Data Protection Regulation ("GDPR") adopted by the European Union and the California Privacy Rights Act ("CRPA") and the California Consumer Privacy Act, as amended by the CRPA (the "CCPA"), can expose us to investigations and enforcement actions by regulatory authorities and claims from individuals potentially resulting in penalties and significant legal liability, if our information technology security efforts are inadequate. In addition, we rely upon

technology suppliers, including cloud-based data management applications hosted by third-party service providers, whose security and information technology systems are subject to similar risks.

Significant disruption in either our or our service providers' or suppliers' information technology or the security of our products could impede 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 talent or are otherwise unsuccessful in the execution of our management succession plans.***

Our continued success depends, in large part, on our ability to hire and retain qualified people and execute on our talent management and succession plans, 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.

***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.

### **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 exposes us to certain financial, economic, political, and other risks, including those listed below.

***Domestic and Global Economic Conditions.*** We have been impacted and may continue to be negatively impacted by general domestic and global economic conditions, although we cannot predict the extent to which such conditions may negatively impact our business. These include, but are not limited to, conditions impacting inflation, credit and capital markets, interest rates, tax law, including tax rate and policy changes, factors

affecting global economic stability, and the political environment relating to health care. 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 United States, 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 “*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 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. The effective dates of implementation, the interactions of tax reforms in multiple jurisdictions, and uncertainty related to dispute resolution mechanisms could impact our provision for income taxes.
- ***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.*** In addition to the factors enumerated above, we are from time to time impacted by a variety of other factors associated with doing business internationally that can harm our future results, including 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;
- military conflict, political unrest, or wars; 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 in which we transact business, have the effect of increasing our reported revenues even when the volume of sales outside of the United States 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 outside of the United States), 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, we 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, including the European Union's European Commission who promulgated the European Medical Device Regulation ("EU MDR"). 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. More specifically relating to the EU MDR which came into effect in May 2017 and became applicable in May 2021 with a staggered transition period, all regulated products must be assessed by notified bodies (organizations designated by EU member states) as to whether they meet the technical requirements of the EU MDR before entering the market in Europe. During the transition period, with the influx of submissions to the notified bodies, any delay on obtaining approvals may result in a disruption of device supply or a further delay in getting a device to market. 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 EU MDR requires a revised MRA. If an MRA covering the EU 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 EU MDR requirements. If these measures are unable to be taken, it may no longer be possible to place such devices on the EU market.

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, the European Commission, 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.

We are also subject to various United States and foreign 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.

In addition, as a global company, we are subject to global data privacy and security laws, regulations and codes of conduct that apply to our businesses. We are required to comply with increasingly complex and changing legal and regulatory requirements that govern the collection, use, storage, security, transfer, disclosure and other processing of personal data in the United States and in other countries, which may include, but are not limited to, The Health Insurance Portability and Accountability Act, as amended (“HIPAA”), The Health Information Technology for Economic and Clinical Health Act, the CCPA, the CRPA, and the GDPR. The GDPR imposes stringent European Union data protection requirements and provides for significant penalties for noncompliance. HIPAA also imposes stringent data privacy and security requirements and the regulatory authority has imposed significant fines and penalties on organizations found to be out of compliance. The CCPA and the CRPA provides consumers with a private right of action against companies who have a security breach due to lack of appropriate security measures. We or our third-party providers and business partners may also be subjected to audits or investigations by one or more domestic or foreign government agencies relating to compliance with information security and privacy laws and regulations, and noncompliance with the laws and regulations could result in substantial and material fines or class action litigation.

Additional risks related to government regulation are also described under “*Health Care Legislation and Other Regulations*” in the risk factor above titled “*Because we operate globally, our business is subject to a variety of risks associated with international sales and operations.*”

***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.

***Climate change, or legal, regulatory or market measures to address climate change, may materially adversely affect our financial condition and business operations.***

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our future operations from natural disasters and extreme weather conditions, such as hurricanes, tornadoes, seismic events, wildfires, or flooding. Such extreme weather conditions could pose physical risks to our facilities and disrupt operation of our supply chain and may impact operational costs. Concern over climate change could result in new legal or regulatory requirements designed to mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory requirements, we may experience increased compliance burdens and costs to meet the regulatory obligations, and it may adversely affect our raw material sourcing, manufacturing operations, and the distribution of our products.

***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

### Asia

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

(1) Owned property.

(2) Leased property.

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, 2023, there were 8,019 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

<u>Period</u>	<u>Total Number of Shares (or Units) Purchased (a)</u>	<u>Average Price Paid per Share (or Unit)</u>	<u>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions) (b)</u>
October 1, 2022 through October 31, 2022 . . . . .	1,381,903	\$83.66	1,381,903	\$1,666.0
November 1, 2022 through November 30, 2022 . .	8,284,153	72.91	8,283,860	1,061.6
December 1, 2022 through December 31, 2022 . .	2,003,416	72.91	2,003,416	915.6
Total . . . . .	<u>11,669,472</u>	74.18	<u>11,669,179</u>	

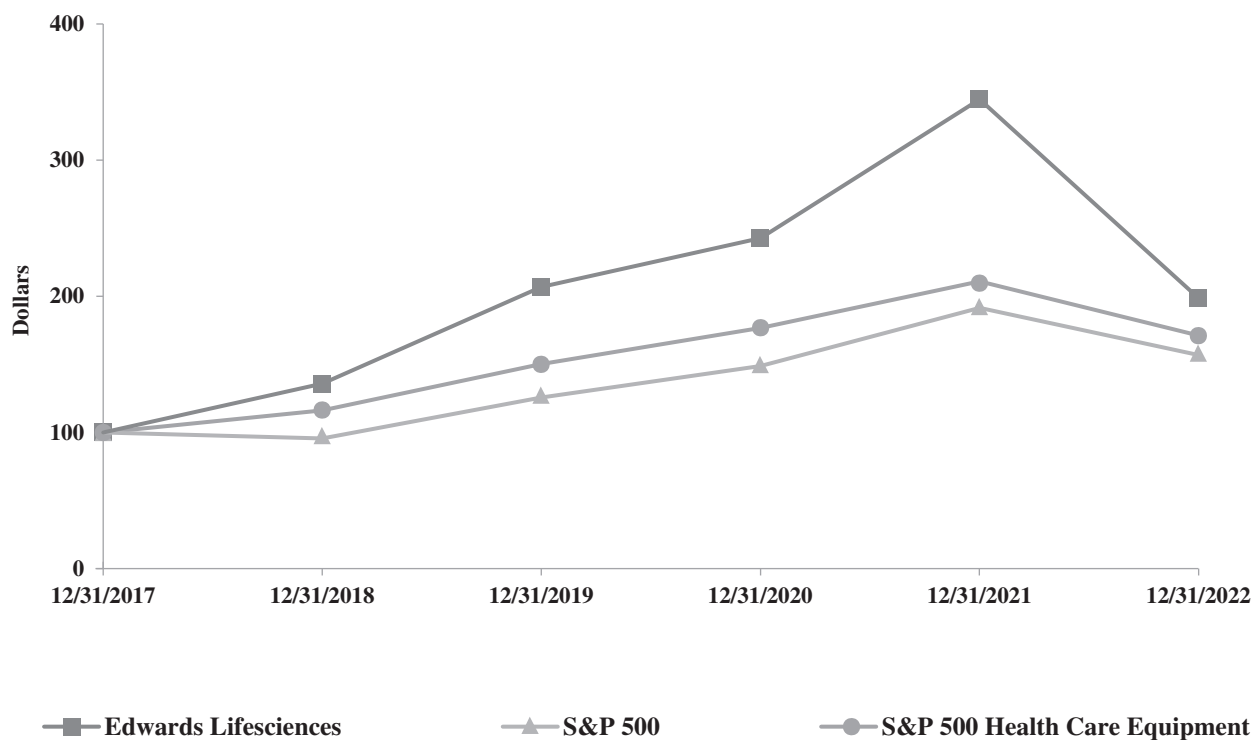
- (a) The difference between the total number of shares (or units) purchased and the total number of shares (or units) purchased as part of publicly announced plans or programs is due to shares withheld by us to satisfy tax withholding obligations in connection with the vesting of restricted stock units issued to employees.
- (b) On May 4, 2021, the Board of Directors approved a stock repurchase program providing for up to \$1.0 billion of repurchases of our common stock. In July 2022, the Board of Directors approved an additional \$1.5 billion of repurchases of our common stock under this program, effective July 28, 2022. Repurchases under the program may be made on the open market, including pursuant to a Rule 10b5-1 plan, and in privately negotiated transactions. The repurchase program does not have an expiration date.



*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, 2017 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				
	2018	2019	2020	2021	2022
Edwards Lifesciences	\$135.90	\$206.98	\$242.83	\$344.82	\$198.59
S&P 500	95.62	125.72	148.85	191.58	156.89
S&P 500 Health Care Equipment	116.24	150.32	176.83	211.05	171.25

**Item 6. [Reserved]**

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

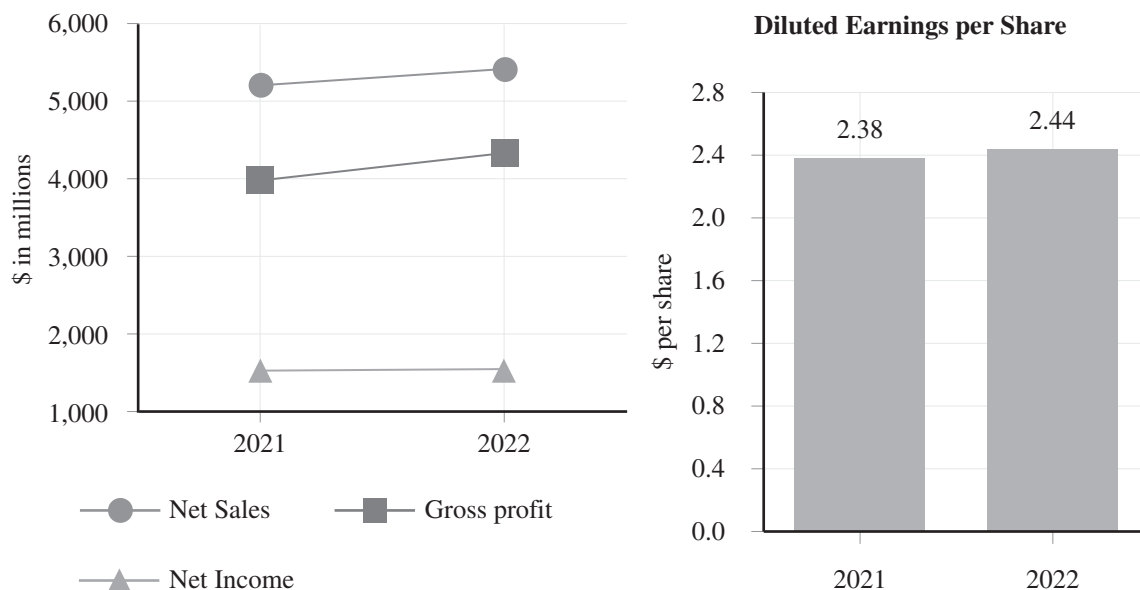
The following discussion and analysis presents the factors that had a material effect on our results of operations during the two years ended December 31, 2022. Also discussed is our financial position as of December 31, 2022. You should read this discussion in conjunction with the historical consolidated financial statements and related notes included elsewhere in this Form 10-K. For a discussion related to the results of operations for 2021 compared to 2020 and a discussion related to our consolidated cash flows for 2021 compared to 2020, refer to Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2021 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 14, 2022.

**Overview**

We are the global leader in patient-focused medical innovations for structural heart disease and critical care monitoring. Driven by a passion to help patients, we partner with the world’s leading clinicians and researchers

and invest in research and development to transform care for those impacted by structural heart disease or who require hemodynamic monitoring during surgery or in intensive care. We conduct operations worldwide and are managed in the following geographical regions: United States, Europe, Japan, and Rest of World. Our products are categorized into the following areas: Transcatheter Aortic Valve Replacement (“TAVR”), Transcatheter Mitral and Tricuspid Therapies (“TMTT”), Surgical Structural Heart (“Surgical”), and Critical Care.

### Financial Highlights and Market Update



### COVID-19 and Macroeconomic Uncertainties

The COVID-19 pandemic has adversely impacted, and may 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 maintain access for patients to our life-saving technologies while providing continuous front-line support to our clinician partners, and protecting the well-being of our employees. 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 to address potential supply constraints.

During the first quarter of 2021, COVID-19 stressed the global healthcare system during the winter months. However, we saw strong recovery beginning in the second quarter of 2021 as widespread vaccine adoption contributed to an increased number of patients. However, the Delta variant had a significant impact on hospital resources during the last two months of the third quarter of 2021, and the Omicron variant had a significant impact during December 2021, especially in the United States.

During the first quarter of 2022, the Omicron variant had a pronounced impact on hospital capacity, resources, and procedure volumes in January 2022, especially in the United States. Our 2022 sales were also impacted by slower than expected improvement in United States hospital staffing shortages and foreign currency headwinds. In the second half of 2022, we faced COVID-19 headwinds in Japan, which created significant strain on hospital capacity.

In addition to the impacts described above, the global economy, including the financial and credit markets, has recently experienced extreme volatility and disruptions, including increases to inflation rates, rising interest

rates, declines in consumer confidence, declines in economic growth, and uncertainty about economic stability. The severity and duration of the impact of these conditions on our business cannot be predicted. See Item 1A, “*Risk Factors*,” for additional information.

### 2022 Financial Highlights

Despite the challenges to our business in 2022 due to COVID-19 and macroeconomic factors, our net sales for 2022 were \$5.4 billion, representing an increase of \$149.9 million over 2021, driven by sales growth of our TAVR products.

Our gross profit increase in 2022 was driven by our sales growth and the positive impact of our foreign currency hedging program.

The increase in our diluted earnings per share in 2022 was driven by a) the aforementioned increase in our gross profit and b) a decrease in our diluted weighted-average shares outstanding, driven by our increased share repurchase activity. This increase was partially offset by a) changes in the fair value of our contingent consideration liabilities, which resulted in a \$121.6 million after tax gain in 2021 compared to a \$35.0 million after tax gain in 2022, b) an after-tax charge of \$47.0 million in 2022, primarily related to the impairment of intangible assets resulting from our decision to exit our *HARPOON* surgical mitral repair system program, and c) increased sales and marketing and research and development expenses in 2022.

### 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. Despite the challenges of the COVID-19 pandemic, our dedicated field teams have found creative ways to support physicians, our engineers continued to advance innovation, and our colleagues worked diligently to keep our clinical trials on track. In 2022, we invested 17.6% of our net sales in research and development. The following is a summary of important developments during 2022:

- we received United States Food and Drug Administration (“FDA”) approval for the *MITRIS RESILIA* valve, a tissue valve replacement specifically designed for the heart’s mitral position;
- we received CE Mark approval for the *PASCAL Precision* transcatheter valve repair system for patients suffering from mitral and tricuspid regurgitation, and FDA approval for *PASCAL Precision* for patients with degenerative mitral regurgitation; and
- we launched the *SAPIEN 3 Ultra RESILIA* valve following FDA approval.

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	
	2022	2021	\$	%
United States .....	\$3,132.6	\$2,963.1	\$169.5	5.7%
Europe .....	1,174.8	1,190.3	(15.5)	(1.3)%
Japan .....	473.6	528.9	(55.3)	(10.4)%
Rest of World .....	601.4	550.2	51.2	9.3%
Outside of the United States .....	2,249.8	2,269.4	(19.6)	(0.9)%
Total net sales .....	\$5,382.4	\$5,232.5	\$149.9	2.9%

Net sales outside of the United States 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.*”

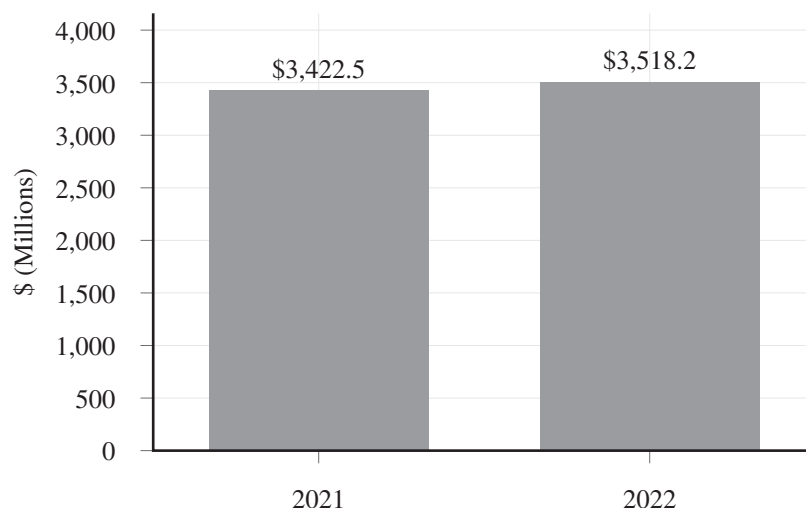
### Net Sales by Product Group

(dollars in millions)

	Years Ended December 31,		Change	
	2022	2021	\$	%
Transcatheter Aortic Valve Replacement .....	\$3,518.2	\$3,422.5	\$ 95.7	2.8%
Transcatheter Mitral and Tricuspid Therapies .....	116.1	86.0	30.1	35.1%
Surgical Heart Valve Therapy .....	893.1	889.1	4.0	0.4%
Critical Care .....	855.0	834.9	20.1	2.4%
Total net sales .....	\$5,382.4	\$5,232.5	\$149.9	2.9%

### *Transcatheter Aortic Valve Replacement*

For the years ended December 31, 2022 and 2021:



The increase in net sales of TAVR products was driven by:

- higher sales of the *Edwards SAPIEN* platform in 2022, primarily the *Edwards SAPIEN 3 Ultra* valve in the United States, Europe, and Rest of World, the *Edwards SAPIEN 3 Ultra RESILIA* valve in the United States, and the *Edwards SAPIEN 3* in Japan;

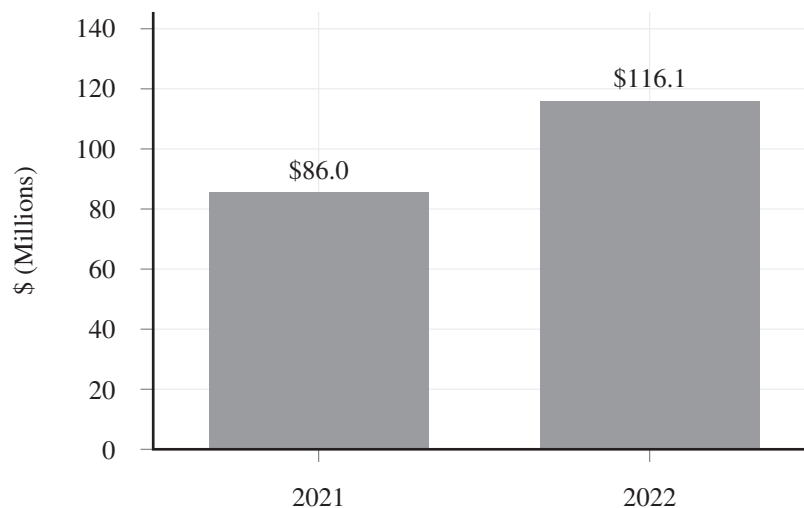
partially offset by:

- foreign currency exchange rate fluctuations, which decreased net sales outside of the United States by \$140.2 million primarily due to the weakening of the Euro and the Japanese yen against the United States dollar.

During 2022, we continued to advance our EARLY TAVR pivotal trial, studying the treatment of severe aortic stenosis patients before their symptoms develop, and our PROGRESS pivotal trial, studying moderate aortic stenosis patients. During the second quarter of 2022, we began treating patients in our ALLIANCE pivotal trial, studying our next-generation TAVR technology, *SAPIEN X4*, and during the fourth quarter of 2022, we began the introduction of the *SAPIEN 3 Ultra Resilia* valve in the United States.

### ***Transcatheter Mitral and Tricuspid Therapies***

For the years ended December 31, 2022 and 2021:

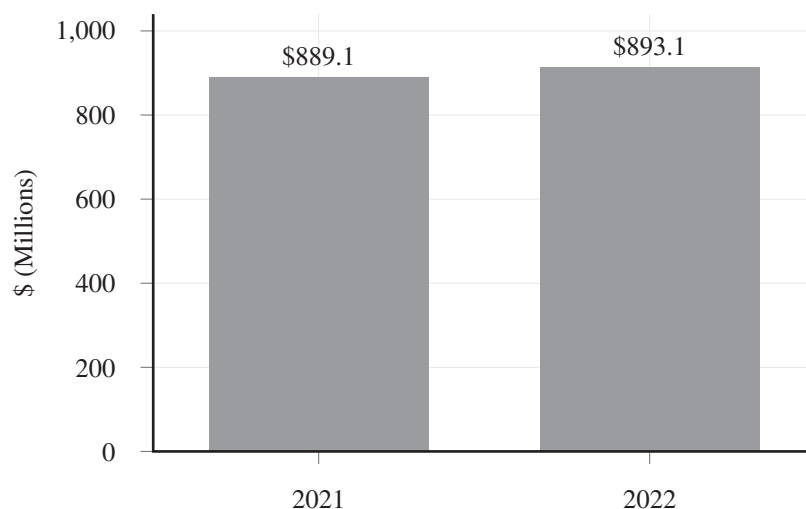


The increase in net sales of TMTT products was due primarily to continued adoption of our *PASCAL* system in Europe.

During August 2022, we received European regulatory approval for *PASCAL Precision* for patients suffering from mitral and tricuspid regurgitation, and in September 2022, we received FDA approval for *PASCAL Precision* for patients with degenerative mitral regurgitation. In mitral replacement, we continued to treat patients through the ENCIRCLE pivotal trial for *SAPIEN M3* and completed enrollment in the MISCEND early feasibility study for *EVOQUE Eos*. We also continued to make progress in enrolling the TRISCEND II pivotal trial of the *EVOQUE* replacement system and the CLASP IITR pivotal trial with the *PASCAL* repair system in patients with symptomatic, severe tricuspid regurgitation.

### ***Surgical Structural Heart***

For the years ended December 31, 2022 and 2021:

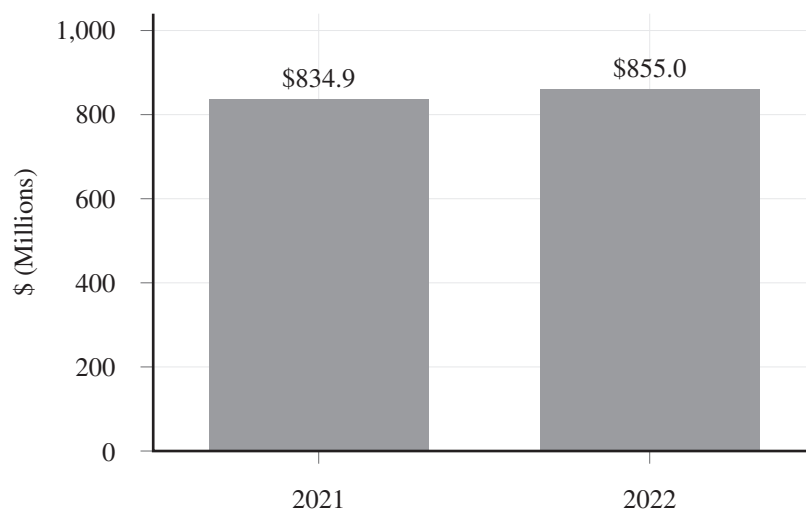


The increase in net sales of Surgical products was due primarily to strong adoption of the *INSPIRIS RESILIA* aortic valve, primarily in the United States and Europe, and the *MITRIS RESILIA* valve, primarily in the United States. These increases were partially offset by the impact of foreign currency exchange rate fluctuations, which decreased net sales outside of the United States by \$46.5 million primarily due to the weakening of the Euro and the Japanese yen against the United States dollar.

In March 2022, we received FDA approval for the *MITRIS RESILIA* valve and initiated the product launch in the United States in April 2022. *MITRIS RESILIA* is a tissue valve replacement specifically designed for the heart's mitral position and incorporates our advanced *RESILIA* technology. In early 2023, we began enrolling patients in our MOMENTS clinical study to demonstrate the durability of *RESILIA* tissue in the mitral position.

### ***Critical Care***

For the years ended December 31, 2022 and 2021:





The increase in net sales of Critical Care products was driven by:

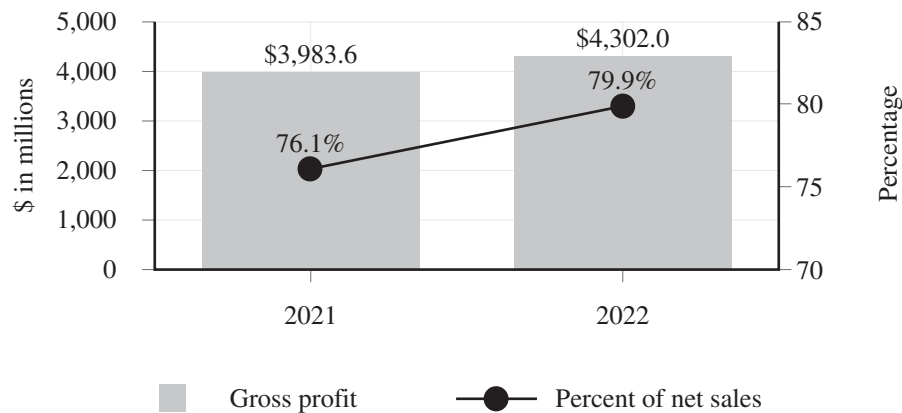
- increased demand for our capital products, primarily the *HemoSphere* monitoring platform in the United States and Japan;
- increased demand for our pressure monitoring products, primarily in the United States; and
- increased demand for our enhanced surgical recovery products, primarily in the United States;

partially offset by:

- foreign currency exchange rate fluctuations, which decreased net sales outside of the United States by \$39.5 million primarily due to the weakening of the Japanese yen and the Euro against the United States dollar.

### Gross Profit

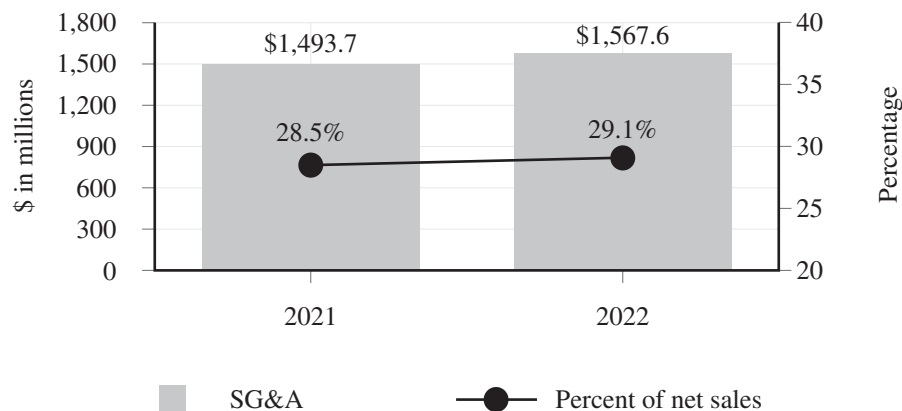
For the years ended December 31, 2022 and 2021:



The increase in gross profit as a percentage of net sales in 2022 compared to 2021 was driven primarily by a 3.6 percentage point increase from the impact of our foreign currency hedging program, which includes hedge contract gains and natural hedges (primarily the strengthening of the United States dollar against the Euro and the Japanese yen).

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

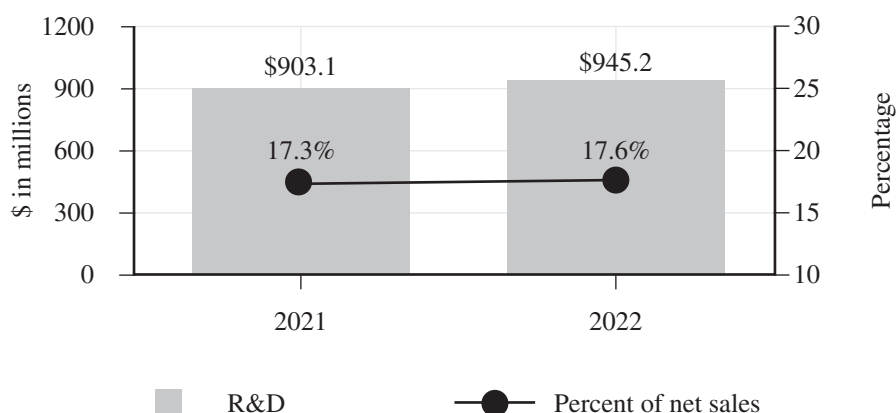
For the years ended December 31, 2022 and 2021:



SG&A expenses increased in 2022 compared to 2021 due primarily to a resumption of in-person commercial activities following COVID-19 and higher field-based personnel-related costs, primarily TAVR and TMTT in the United States. Foreign currency exchange rate fluctuations decreased expenses by \$63.1 million due primarily to the strengthening of the United States dollar against the Euro and the Japanese yen.

### Research and Development (“R&D”) Expenses

For the years ended December 31, 2022 and 2021:



R&D expenses increased marginally in 2022 compared to 2021 due primarily to continued investments in our transcatheter innovations, including increased clinical trial activity.

### Change in Fair Value of Contingent Consideration Liabilities, net

The change in fair value of contingent consideration liabilities resulted in income of \$35.8 million and \$124.1 million in 2022 and 2021, respectively. The income in 2022 was due to changes in projected probabilities of milestone achievement and our decision in the third quarter of 2022 to exit our *HARPOON* surgical mitral repair system program. The income in 2021 was attributable to changes in the projected probabilities of milestone achievements and the projected timing of cash inflows from product sales.

### Special Charge

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

### Interest Expense

Interest expense was \$19.2 million and \$18.4 million in 2022 and 2021, respectively. The increase in interest expense resulted primarily from lower capitalized interest due to decreased facilities construction.

### Interest Income

Interest income was \$35.5 million and \$17.4 million in 2022 and 2021, respectively. The increase in interest income resulted primarily from a higher average yield on our investments.

**Other Income, net**  
(in millions)

	<b>Years Ended December 31,</b>	
	<u>2022</u>	<u>2021</u>
Foreign exchange losses (gains), net . . . . .	\$ 1.2	\$ (5.0)
Gain on insurance settlement . . . . .	(3.8)	—
Loss (gain) on investments . . . . .	1.1	(5.8)
Non-service cost components of net periodic pension benefit cost . . . . .	(1.1)	0.3
Other . . . . .	<u>—</u>	<u>(2.2)</u>
Total other income, net . . . . .	<u>\$ (2.6)</u>	<u>\$ (12.7)</u>

The net foreign exchange losses (gains) relate to the foreign currency fluctuations primarily in our global trade and intercompany receivable and payable balances, partially offset by the gains and losses on foreign currency derivative instruments.

The gain on insurance settlement relates to an insurance recovery for damaged cargo shipments of heart valves.

The loss (gain) on investments primarily represents our net share of gains and losses in investments accounted for under the equity method, and realized gains and losses on investments in equity securities.

The non-service cost components of net periodic pension benefit cost includes the costs or gains 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**  
(\$ in millions)

	<b>Years Ended December 31,</b>		<b>Change</b>	
	<u>2022</u>	<u>2021</u>	<u>\$</u>	<u>%</u>
Provision for income taxes . . . . .	\$245.5	\$198.9	\$46.6	23.4%
Effective tax rate . . . . .	13.9%	11.7%		

Our effective income tax rate in 2022 and 2021 was 13.9% and 11.7%, respectively. Our effective tax rate for 2022 increased in comparison to 2021 primarily due to the decrease in the tax benefit from the change in fair value of contingent consideration liabilities and the decrease in the excess tax benefit from employee share-based compensation.

In 2022, the difference between our 13.9% effective tax rate and the Federal statutory rate of 21% was primarily due to (1) foreign earnings taxed at lower rates, (2) Federal and California research and development credits, (3) the excess tax benefit from employee share-based compensation and (4) the tax benefit from the change in fair value of contingent consideration liabilities.

As of December 31, 2022, we had \$189.8 million of gross 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 into the distant future.

As of December 31, 2022, our gross uncertain tax positions were \$475.3 million. We estimate that these liabilities would be reduced by \$182.1 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 \$293.2 million, if not required, would favorably affect our effective tax rate.

In the normal course of business, the Internal Revenue Service (“IRS”) and other taxing authorities are in different stages of examining various years of our tax filings. During these audits, we may receive proposed audit adjustments that could be material. Therefore, there is a possibility that an adverse outcome in these audits could have a material effect on our results of operations and financial condition. 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 eventual 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 for any adjustments that may result from our uncertain tax positions.

We executed an Advance Pricing Agreement (“APA”) in 2018 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 (collectively “Surgical/TAVR”) intercompany royalty transactions, then reverted to IRS examination for further consideration as part of the respective years’ regular tax audits. In addition, we executed other bilateral 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 all the APAs which cover transactions with Japan for the years 2020 and forward. An APA between Switzerland and Japan covering tax years 2020 through 2024 was executed in 2021. The execution of the other APA renewals depends on many variables outside of our control.

At December 31, 2022, 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 India for years from 2010 and on.

The audits of our United States federal income tax returns through 2014 have been closed. The IRS fieldwork for the 2015 through 2017 tax years was completed during the second quarter of 2021, except for transfer pricing and related matters. The IRS began its examination of the 2018 through 2020 tax years during the first quarter of 2022.

During 2021, we received a Notice of Proposed Adjustment (“NOPA”) from the IRS for the 2015-2017 tax years relating to transfer pricing involving certain Surgical/TAVR intercompany royalty transactions between our United States and Switzerland subsidiaries. The NOPA proposes an increase to our United States taxable income, which could result in additional tax expense for this period of approximately \$210 million and represents a significant change to previously agreed upon transfer pricing methodologies for these types of transactions. We have formally disagreed with the NOPA and submitted a formal protest on the matter during the fourth quarter of 2021. During the second quarter of 2022, we received the IRS’s rebuttal to our protest and were notified that the case had been transferred to the IRS Independent Office of Appeals. The opening conference is scheduled for the first quarter of 2023. We continue to evaluate all possible remedies available to us, which could take several years to resolve. We believe the amounts previously accrued related to this uncertain tax position are sufficient and, accordingly, have not accrued any additional amount based on the NOPA received. While no payment of any amount related to the NOPA is required to be made, if at all, until all applicable proceedings have been completed, we made an advance payment of tax in November 2022 to prevent the further accrual of interest on any potential deficiency.

Certain Surgical/TAVR intercompany royalty transactions covering tax years 2015 through 2022 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, 2022. We have considered this information, as well as information regarding the NOPA and rebuttal described above, in our evaluation of our uncertain tax positions. The impact of 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 in our existing uncertain tax positions may occur in the next 12 months and, therefore, have continued to record the uncertain tax positions as a long-term liability.

On August 16, 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law. The IRA includes, among other provisions, changes to the U.S. corporate income tax system, including (1) a 15% minimum tax based on “adjusted financial statement income,” which is effective for tax years beginning after December 31, 2022, and (2) a one percent excise tax on net repurchases of stock after December 31, 2022. While we continue to evaluate the IRA and its application to our business, we do not expect the IRA will have a material impact on our consolidated financial statements.

We have received tax incentives in certain non-United States tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were \$247.4 million (\$0.40 per diluted share) and \$208.0 million (\$0.33 per diluted share) for the years ended December 31, 2022 and 2021, respectively.

### **Liquidity and Capital Resources**

Our sources of cash liquidity include cash and cash equivalents, short-term investments, cash from operations, and amounts available under credit facilities. We believe that these sources are sufficient to fund the current and long-term requirements of working capital, capital expenditures, and other financial commitments. 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”) 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 three remaining annual installments, as outlined in the contractual obligations table presented under “Material Cash Requirements” below. As of December 31, 2022, we had a remaining tax obligation of \$188.5 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, 2022, cash and cash equivalents and short-term investments held in the United States and outside of the United States were \$731.8 million and \$483.5 million, respectively. During 2022, we repatriated cash of \$934.0 million. We assert that \$1.0 billion of our foreign earnings continue to be permanently reinvested and our intent is to repatriate \$580.8 million of our foreign earnings as of December 31, 2022. The estimated net tax liability on the indefinitely reinvested earnings if repatriated is \$14.9 million.

We had a Five-Year Credit Agreement (the “Prior Credit Agreement”) which was scheduled to mature on April 28, 2023 and provided up to an aggregate of \$750.0 million in borrowings in multiple currencies. In July 2022, we entered into a new Five-Year Credit Agreement (the “New Credit Agreement”) which provides for a \$750.0 million multi-currency unsecured revolving credit facility and replaced the Prior Credit Agreement. The New Credit Agreement matures on July 15, 2027. We may increase the amount available under the New Credit Agreement by up to an additional \$250.0 million in the aggregate and extend the maturity date for an additional year, subject to agreement of the lenders. The New Credit Agreement contains various financial and other covenants, including a maximum leverage ratio, as defined in the agreement. As of December 31, 2022, no amounts were outstanding, and we were in compliance with all covenants under the New Credit Agreement.

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, 2022, we have not elected to redeem any of the 2018 Notes. As of December 31, 2022, the carrying value of the 2018 Notes was \$596.3 million. For further information on our debt, see Note 10 to the “*Consolidated Financial Statements.*”

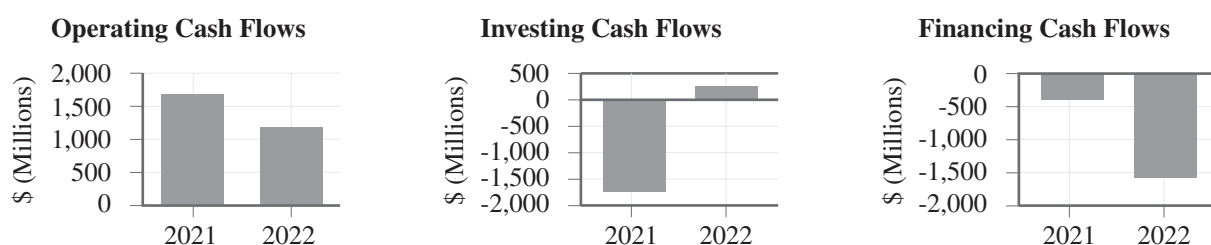
From time to time, we repurchase shares of our common stock under share repurchase programs authorized by the Board of Directors. We consider several factors in determining when to execute share repurchases, including, among other things, expected dilution from stock plans, cash capacity, and the market price of our common stock. During 2022, under the Board authorized repurchase program, we repurchased a total of 20.0 million shares at an aggregate cost of \$1.7 billion. As of December 31, 2022, we had remaining authority to purchase \$915.6 million of our common stock under the share repurchase program.

Certain of our business acquisitions involve contingent consideration arrangements. Payment of additional consideration in the future may be required, contingent upon the acquired business reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. For further information, see Note 11 to the “*Consolidated Financial Statements.*”

We have purchased options to acquire and have agreed to provide promissory notes to various entities. These arrangements could result in additional cash outlays in the future should we decide to exercise the options or should the entities draw on the promissory notes. For further information, see Note 8 to the “*Consolidated Financial Statements.*”

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 \$70 million. We made a one-time \$100.0 million payment to Abbott in July 2020, and are making quarterly payments in subsequent years. For further information, see Note 3 to the “*Consolidated Financial Statements.*”

**Consolidated Cash Flows—For the twelve months ended December 31, 2022 and 2021**



Net cash flows provided by **operating activities** of \$1.2 billion for 2022 decreased \$513.9 million from 2021 due to an increase in tax payments, an increase in inventory builds compared to the prior year, and a higher bonus payout in 2022 associated with 2021 performance.

Net cash provided by **investing activities** of \$252.3 million in 2022 consisted primarily of net proceeds from investments of \$661.0 million, partially offset by capital expenditures of \$244.6 million and payments of \$109.6 million for options to acquire other companies. For further information, see Note 8 to the “*Consolidated Financial Statements.*”

Net cash used in investing activities of \$1.7 billion in 2021 consisted primarily of net purchases of investments of \$1.4 billion and capital expenditures of \$325.8 million.



We currently anticipate making capital expenditures of approximately \$300.0 million in 2023 as we continue to invest in our operations.

Net cash used in **financing activities** of \$1.6 billion in 2022 consisted primarily of purchases of treasury stock of \$1.7 billion, partially offset by proceeds from stock plans of \$146.4 million.

Net cash used in financing activities of \$356.3 million in 2021 consisted primarily of purchases of treasury stock of \$512.8 million, partially offset by proceeds from stock plans of \$158.6 million.

### **Material Cash Requirements**

A summary of our material cash requirements as of December 31, 2022 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	102.7	27.0	31.0	18.7	26.0
Interest on debt	106.4	19.6	39.3	38.9	8.6
Transition tax on unremitted foreign earnings and profits (a)	188.5	47.1	141.4	—	—
Litigation settlement obligation (minimum payments)	162.5	50.0	100.0	12.5	—
Pension obligations (b)	2.4	2.4	—	—	—
Purchase and other commitments (c)	34.3	18.5	12.0	2.8	1.0
Total contractual cash obligations (d), (e)	<u>\$1,196.8</u>	<u>\$164.6</u>	<u>\$323.7</u>	<u>\$72.9</u>	<u>\$635.6</u>

- (a) As of December 31, 2022, we had recorded \$188.5 million of income tax liabilities related to the one-time transition tax that resulted from the enactment of the 2017 Act. The transition tax is due in eight annual installments, with the first five installments paid in 2018 through 2022. The remaining installment amounts will be equal to 15% of the total liability payable in 2023, 20% in 2024, and 25% in 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, 2022 was \$23.5 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, 2022, the gross liability for uncertain tax positions, including interest, was \$519.8 million and relates primarily to transfer pricing matters which are discussed in detail in Note 17 to the “*Consolidated Financial Statements*.” Based upon the information currently available and numerous possible outcomes, we cannot reasonably estimate 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 judgments and estimates. These matters that are subject to judgments and estimates 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.

### ***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; and
- projected payment dates.

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 United States 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, 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. 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 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. If a reasonable estimate of a known or probable loss cannot be made, but a range of probable losses can be estimated, the low-end of the range of losses is recognized if no amount within the range is a better estimate than any other. If we determine that a loss is possible, but not probable, and the range of the loss can be reasonably determined, then we disclose the range of the possible loss. 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, United States 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, 2022, we had \$1.6 billion of investments in debt securities which had an average remaining term to maturity of 0.98 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, 2022 would have resulted in a \$7.8 million to \$15.5 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, 2022, we had \$600.0 million of 2018 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 Secured Overnight Financing Rate (“SOFR”). As of December 31, 2022, there were no borrowings outstanding under the Credit Agreement. Based on our December 31, 2022 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, 2022, a hypothetical 1.0% absolute increase in market interest rates would decrease the fair value of the fixed-rate debt by approximately \$26.7 million. This hypothetical change in interest rates would not impact the interest expense on the fixed-rate debt.

For more information related to outstanding debt obligations, see Note 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, 2022 was \$2.0 billion. A hypothetical 10% increase (or decrease) in the value of the United States dollar against all hedged currencies would increase (or decrease) the fair value of these derivative contracts by \$158.2 million. Any gains or losses on the fair value of derivative contracts would generally be offset by gains and losses on the underlying transactions, so the net impact would not be significant to our financial condition or results of operations.

For more information related to outstanding foreign exchange contracts, see Note 2 and Note 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, 2022, 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 2022, 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, 2022, we had \$1.6 billion of investments in debt securities of various companies, of which \$1.1 billion were long-term. In addition, we had \$108.3 million of investments in equity instruments. Should these companies experience a decline in financial performance, financial condition or credit capacity, or fail to meet certain development milestones, 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, 2022**

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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, 2022 and 2021, 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, 2022, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 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, 2022, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the COSO.

### ***Basis for Opinions***

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

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

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

### ***Definition and Limitations of Internal Control over Financial Reporting***

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in

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

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

### ***Critical Audit Matter***

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

### ***Uncertain Tax Positions Related to Intercompany Transfer Pricing***

As described in Note 17 to the consolidated financial statements, the Company had an uncertain gross tax position liability balance of \$475.3 million as of December 31, 2022, of which a majority is related to intercompany transfer pricing. As disclosed by management, the Company is subject to income taxes in the United States and numerous foreign jurisdictions. 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 estimating the ultimate resolution to intercompany pricing controversies between countries when there are numerous possible outcomes. 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. In addition, 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 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 related to intercompany transfer pricing, including US federal filing positions, and the related final income 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 management's

assessment of possible outcomes of uncertain tax positions related to intercompany transfer pricing controversies between countries; 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 accurate 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 tax benefit to be realized, and the application of relevant tax laws.

/s/ PricewaterhouseCoopers LLP  
Irvine, California  
February 13, 2023

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

**EDWARDS LIFESCIENCES CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

(in millions, except par value)

	December 31,	
	2022	2021
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 769.0	\$ 862.8
Short-term investments (Note 7)	446.3	604.0
Accounts receivable, net of allowances of \$7.9 and \$9.3, respectively	643.0	582.2
Other receivables	56.1	82.7
Inventories (Note 5)	875.5	726.7
Prepaid expenses	110.0	85.2
Other current assets	195.9	237.1
Total current assets	3,095.8	3,180.7
Long-term investments (Note 7)	1,239.0	1,834.2
Property, plant, and equipment, net (Note 5)	1,632.8	1,546.6
Operating lease right-of-use assets (Note 6)	92.3	92.1
Goodwill (Note 9)	1,164.3	1,167.9
Other intangible assets, net (Note 9)	285.2	323.6
Deferred income taxes	484.0	246.7
Other assets	299.1	110.8
Total assets	\$ 8,292.5	\$ 8,502.6
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 201.9	\$ 204.5
Accrued and other liabilities (Note 5)	795.0	802.3
Operating lease liabilities (Note 6)	25.5	25.5
Total current liabilities	1,022.4	1,032.3
Long-term debt (Note 10)	596.3	595.7
Contingent consideration liabilities (Notes 8 and 11)	26.2	62.0
Taxes payable (Note 17)	143.4	190.0
Operating lease liabilities (Note 6)	69.5	69.1
Uncertain tax positions (Note 17)	267.5	259.0
Litigation settlement accrual (Note 3)	143.0	191.3
Other liabilities	217.5	267.3
Total liabilities	2,485.8	2,666.7
Commitments and contingencies (Notes 6, 10, and 18)		
<b>Stockholders' equity (Note 14)</b>		
Preferred stock, \$0.01 par value, authorized 50.0 shares, no shares outstanding	—	—
Common stock, \$1.00 par value, 1,050.0 shares authorized, 646.3 and 642.0 shares issued, and 608.3 and 624.1 shares outstanding, respectively	646.3	642.0
Additional paid-in capital	1,969.3	1,700.4
Retained earnings	7,590.0	6,068.1
Accumulated other comprehensive loss (Note 15)	(254.9)	(157.7)
Treasury stock, at cost, 38.0 and 17.9 shares, respectively	(4,144.0)	(2,416.9)
Total stockholders' equity	5,806.7	5,835.9
Total liabilities and stockholders' equity	\$ 8,292.5	\$ 8,502.6

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,		
	2022	2021	2020
Net sales	\$5,382.4	\$5,232.5	\$4,386.3
Cost of sales	1,080.4	1,248.9	1,080.6
Gross profit	4,302.0	3,983.6	3,305.7
Selling, general, and administrative expenses	1,567.6	1,493.7	1,228.4
Research and development expenses	945.2	903.1	760.7
Intellectual property litigation expenses, net (Note 3)	15.8	20.6	405.4
Change in fair value of contingent consideration liabilities, net (Note 11)	(35.8)	(124.1)	13.6
Special charge (Note 4)	60.7	—	—
Operating income	1,748.5	1,690.3	897.6
Interest expense	19.2	18.4	15.8
Interest income	(35.5)	(17.4)	(23.4)
Other income, net (Note 16)	(2.6)	(12.7)	(11.5)
Income before provision for income taxes	1,767.4	1,702.0	916.7
Provision for income taxes (Note 17)	245.5	198.9	93.3
Net income	<u>\$1,521.9</u>	<u>\$1,503.1</u>	<u>\$ 823.4</u>
<b>Share information</b> (Note 2):			
Earnings per share:			
Basic	\$ 2.46	\$ 2.41	\$ 1.32
Diluted	\$ 2.44	\$ 2.38	\$ 1.30
Weighted-average number of common shares outstanding:			
Basic	619.0	623.3	622.6
Diluted	624.2	631.2	631.9

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,		
	2022	2021	2020
Net income .....	\$1,521.9	\$1,503.1	\$823.4
Other comprehensive (loss) income, net of tax (Note 15):			
Foreign currency translation adjustments .....	(46.3)	(50.1)	32.4
Unrealized (loss) gain on hedges .....	(5.9)	57.4	(40.2)
Unrealized pension credits (costs) .....	13.7	11.6	(4.2)
Unrealized (loss) gain on available-for-sale investments .....	(77.5)	(24.1)	6.6
Reclassification of net realized investment loss to earnings .....	18.8	8.6	0.3
Other comprehensive (loss) income, net of tax .....	(97.2)	3.4	(5.1)
Comprehensive income .....	\$1,424.7	\$1,506.5	\$818.3

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,		
	2022	2021	2020
<b>Cash flows from operating activities</b>			
Net income	\$ 1,521.9	\$ 1,503.1	\$ 823.4
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	139.6	134.8	107.2
Non-cash operating lease cost	27.2	28.5	28.2
Stock-based compensation (Notes 2 and 14)	126.8	109.3	92.6
Impairment charges (Note 4)	55.1	4.0	—
Change in fair value of contingent consideration liabilities, net (Note 11)	(35.8)	(124.1)	13.6
Loss (gain) on investments, net	51.5	(36.8)	(21.2)
Deferred income taxes	(254.5)	(41.4)	(49.4)
Other	7.8	9.4	17.7
Changes in operating assets and liabilities:			
Accounts and other receivables, net	(84.1)	(91.1)	41.9
Inventories	(213.4)	19.0	(120.6)
Prepaid expenses and other current assets	0.1	7.9	(28.5)
Accounts payable and accrued liabilities	(21.4)	195.2	(84.5)
Litigation settlement accrual	(45.0)	(29.2)	270.5
Income taxes	(5.6)	62.0	(52.9)
Other	(52.0)	(18.5)	16.3
Net cash provided by operating activities	<u>1,218.2</u>	<u>1,732.1</u>	<u>1,054.3</u>
<b>Cash flows from investing activities</b>			
Capital expenditures	(244.6)	(325.8)	(407.0)
Purchases of held-to-maturity investments (Note 7)	(353.5)	(250.0)	(162.0)
Proceeds from sales and maturities of held-to-maturity investments (Note 7)	419.5	138.0	212.2
Purchases of available-for-sale investments (Note 7)	(315.8)	(1,629.3)	(689.7)
Proceeds from sales and maturities of available-for-sale investments (Note 7)	939.6	391.2	564.8
Payment for acquisition option (Note 8)	(109.6)	(13.1)	(10.0)
Issuances of notes receivable	(52.3)	(5.1)	(27.0)
Collections of notes receivable	18.0	20.0	—
Investments in intangible assets	(20.2)	(4.0)	(0.3)
Other	(28.8)	(44.4)	(12.1)
Net cash provided by (used in) investing activities	<u>252.3</u>	<u>(1,722.5)</u>	<u>(531.1)</u>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of debt	—	5.2	16.2
Payments on debt and finance lease obligations	(0.2)	(7.0)	(17.0)
Purchases of treasury stock	(1,727.1)	(512.8)	(625.4)
Proceeds from stock plans	146.4	158.6	140.5
Other	(3.6)	(0.3)	(1.2)
Net cash used in financing activities	<u>(1,584.5)</u>	<u>(356.3)</u>	<u>(486.9)</u>
Effect of currency exchange rate changes on cash, cash equivalents, and restricted cash	19.2	13.9	(20.5)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(94.8)	(332.8)	15.8
Cash, cash equivalents, and restricted cash at beginning of year	867.4	1,200.2	1,184.4
Cash, cash equivalents, and restricted cash at end of year	<u>\$ 772.6</u>	<u>\$ 867.4</u>	<u>\$1,200.2</u>

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

**EDWARDS LIFESCIENCES CORPORATION**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(in millions)

	<u>Common Stock</u>		<u>Treasury Stock</u>		<u>Additional Paid-in Capital</u>	<u>Retained Earnings</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Par Value</u>	<u>Shares</u>	<u>Amount</u>				
<b>BALANCE AT DECEMBER 31,</b>								
<b>2019</b> .....	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)			—
<b>BALANCE AT DECEMBER 31,</b>								
<b>2020</b> .....	636.4	636.4	12.1	(1,904.1)	1,438.1	4,565.0	(161.1)	4,574.3
Net income .....						1,503.1		1,503.1
Other comprehensive income, net of tax .....							3.4	3.4
Common stock issued under equity plans .....	5.6	5.6			153.0			158.6
Stock-based compensation expense .....					109.3			109.3
Purchases of treasury stock .....			5.8	(512.8)				(512.8)
<b>BALANCE AT DECEMBER 31,</b>								
<b>2021</b> .....	642.0	642.0	17.9	(2,416.9)	1,700.4	6,068.1	(157.7)	5,835.9
Net income .....						1,521.9		1,521.9
Other comprehensive loss, net of tax .....							(97.2)	(97.2)
Common stock issued under equity plans .....	4.3	4.3			142.1			146.4
Stock-based compensation expense .....					126.8			126.8
Purchases of treasury stock .....			20.1	(1,727.1)				(1,727.1)
<b>BALANCE AT DECEMBER 31,</b>								
<b>2022</b> .....	646.3	\$646.3	38.0	\$(4,144.0)	\$1,969.3	\$7,590.0	\$(254.9)	\$ 5,806.7

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 material VIEs; however, future events may require VIEs to be consolidated if the Company becomes the primary beneficiary.

**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.

**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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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.

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 a reduction to 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, 2022 and 2021, \$10.6 million and \$10.2 million, respectively, of deferred revenue associated with outstanding service contracts was recorded in "*Accrued and Other Liabilities*" and "*Other Liabilities*." During 2022, the Company recognized as revenue \$7.2 million that was included in the balance of deferred revenue as of December 31, 2021, and during 2021, the Company recognized as revenue \$7.3 million that was included in the balance of deferred revenue as of December 31, 2020.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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, 2022, 2021, and 2020, shipping costs of \$87.4 million, \$85.3 million, and \$74.0 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 at the time of purchase 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, United States government and agency securities, asset-backed securities, corporate debt securities, and municipal debt 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 3% 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.*"



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 length of time and the extent to which the security's fair value has been below 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.

**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 inception 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 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 and human resources personnel, and information technology. During the years ended December 31, 2022, 2021, and 2020, the Company allocated \$88.1 million, \$77.9 million, and \$63.1 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2022 and 2021 were \$43.7 million and \$33.7 million, respectively.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

At December 31, 2022 and 2021, \$128.6 million and \$125.8 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 \$133.9 million, \$127.0 million, and \$101.8 million for the years ended December 31, 2022, 2021, and 2020, respectively.

**Leases**

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 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.

**Acquisitions**

Businesses that the Company acquires are included in its results of operations as of the acquisition date. The purchase price is allocated to the assets acquired and liabilities assumed based on their estimated fair values. The excess of the purchase price over the fair values of identifiable assets and liabilities is recorded as goodwill. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred. Contingent consideration obligations incurred in connection with a business combination are recorded at their fair values on the acquisition date and remeasured on a quarterly basis, with changes in their fair value

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

recorded as an adjustment to earnings, until the related contingencies have been resolved. When the assets acquired do not meet the definition of a business combination, the transactions is accounted for as an asset acquisition. In an asset acquisition, the cost of the acquisition is allocated to the assets acquired and liabilities assumed based on their relative fair values. Upfront payments related to in-process research and development projects with no alternative future use are expensed upon acquisition.

**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 2022, 2021, and 2020, the Company did not record any goodwill 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 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 2022, the Company recorded a \$52.7 million impairment of certain developed technology and in-process research and development assets. For further information, see Note 4. In 2021 and 2020, the Company did not record any impairment loss related to its in-process research and development assets.

**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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 United States 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 the 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>2022</u>	<u>2021</u>	<u>2020</u>
Basic:			
Net income . . . . .	<u>\$1,521.9</u>	<u>\$1,503.1</u>	<u>\$823.4</u>
Weighted-average shares outstanding . . . . .	<u>619.0</u>	<u>623.3</u>	<u>622.6</u>
Basic earnings per share . . . . .	<u>\$ 2.46</u>	<u>\$ 2.41</u>	<u>\$ 1.32</u>
Diluted:			
Net income . . . . .	<u>\$1,521.9</u>	<u>\$1,503.1</u>	<u>\$823.4</u>
Weighted-average shares outstanding . . . . .	619.0	623.3	622.6
Dilutive effect of stock plans . . . . .	<u>5.2</u>	<u>7.9</u>	<u>9.3</u>
Dilutive weighted-average shares outstanding . . . . .	<u>624.2</u>	<u>631.2</u>	<u>631.9</u>
Diluted earnings per share . . . . .	<u>\$ 2.44</u>	<u>\$ 2.38</u>	<u>\$ 1.30</u>

Outstanding stock options, unvested restricted stock units, and unvested market-based restricted stock units to purchase approximately 3.6 million, 1.8 million, and 2.0 million shares for the years ended December 31, 2022, 2021, and 2020, respectively, 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 and market-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 each award's requisite service period (vesting period) on a straight-line basis. 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.

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

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Cost of sales . . . . .	\$ 22.8	\$ 20.4	\$ 17.2
Selling, general, and administrative expenses . . . . .	75.3	65.6	56.6
Research and development expenses . . . . .	<u>28.7</u>	<u>23.3</u>	<u>18.8</u>
Total stock-based compensation expense . . . . .	126.8	109.3	92.6
Income tax benefit . . . . .	<u>(21.6)</u>	<u>(18.9)</u>	<u>(15.4)</u>
Total stock-based compensation expense, net of tax . . . .	<u>\$105.2</u>	<u>\$ 90.4</u>	<u>\$ 77.2</u>

Upon a participant's retirement, all unvested stock options 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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 its currency exchange rate risk and its interest rate risk. 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 and cross currency swap contracts 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 the revaluation of 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 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.



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Recently Adopted Accounting Standards**

In November 2021, the Financial Accounting Standards Board (“FASB”) issued an amendment to the accounting guidance on government assistance. The guidance requires certain disclosures about transactions with a government that are accounted for by applying a grant or contribution model. The guidance was effective for annual periods beginning after December 15, 2021. The adoption of this guidance was applied prospectively and did not have an 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 \$15.8 million, \$20.6 million and \$405.4 million during 2022, 2021 and 2020, respectively.

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. 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 \$70 million. The Company made a one-time \$100.0 million payment to Abbott in July 2020, and is making quarterly payments in subsequent years. As of December 31, 2022, \$53.3 million was accrued in “*Accrued and other liabilities*” and \$143.0 million was accrued in “*Litigation settlement accrual*” on the consolidated balance sheet.

**4. SPECIAL CHARGE**

In September 2022, the Company decided to exit its *HARPOON* surgical mitral repair system program. As a result, the Company recorded a charge to its United States segment of \$62.3 million, of which \$60.7 million was included in “*Special Charge*” and \$1.6 million was included in “*Cost of Sales*” on the consolidated statements of operations. The charge primarily related to the full impairment of intangible assets associated with the technology for \$52.7 million (see Note 8 and Note 9) and other related exit costs. The Company believes that no additional contingent consideration is due and, in September 2022, recorded an \$11.7 million contingent consideration gain associated with the exit (see Note 11).

**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>2022</u>	<u>2021</u>
	(in millions)	
<b>Inventories</b>		
Raw materials . . . . .	\$ 156.4	\$ 132.8
Work in process . . . . .	177.4	164.3
Finished products . . . . .	541.7	429.6
	<u>\$ 875.5</u>	<u>\$ 726.7</u>
<b>Property, plant, and equipment, net</b>		
Land . . . . .	\$ 116.3	\$ 116.5
Buildings and leasehold improvements . . . . .	1,189.2	1,010.1
Machinery and equipment . . . . .	697.6	613.4
Equipment with customers . . . . .	37.4	39.2
Software . . . . .	87.5	88.2
Construction in progress . . . . .	255.2	333.8
	2,383.2	2,201.2
Accumulated depreciation . . . . .	(750.4)	(654.6)
	<u>\$1,632.8</u>	<u>\$1,546.6</u>
<b>Accrued and other liabilities</b>		
Employee compensation and withholdings . . . . .	\$ 268.7	\$ 319.7
Accrued rebates . . . . .	116.1	77.0
Property, payroll, and other taxes . . . . .	45.6	68.9
Research and development accruals . . . . .	66.9	58.2
Legal and insurance (Notes 3 and 18) . . . . .	81.4	79.1
Taxes payable . . . . .	50.6	30.6
Fair value of derivatives . . . . .	20.7	3.9
Accrued marketing expenses . . . . .	17.0	20.1
Accrued professional services . . . . .	6.6	11.9
Accrued realignment reserves . . . . .	15.6	19.1
Accrued relocation costs . . . . .	25.2	26.2
Other accrued liabilities . . . . .	80.6	87.6
	<u>\$ 795.0</u>	<u>\$ 802.3</u>

**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>2022</u>	<u>2021</u>	<u>2020</u>
Cash paid during the year for:			
Interest .....	\$ 19.3	\$ 20.2	\$ 19.9
Income taxes .....	\$504.1	\$182.5	\$197.9
Amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases .....	\$ 28.1	\$ 31.9	\$ 29.7
Non-cash investing and financing transactions:			
Right-of-use assets obtained in exchange for new lease liabilities .....	\$ 31.9	\$ 28.7	\$ 39.7
Capital expenditures accruals .....	\$ 42.6	\$ 54.3	\$ 80.4
Conversion of notes receivable to equity investment .....	\$ —	\$ 21.5	\$ 4.5

*Cash, Cash Equivalents, and Restricted Cash*

(in millions)

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Cash and cash equivalents .....	\$769.0	\$862.8	\$1,183.2
Restricted cash included in other current assets .....	0.5	1.5	16.6
Restricted cash included in other assets .....	3.1	3.1	0.4
Total cash, cash equivalents, and restricted cash .....	<u>\$772.6</u>	<u>\$867.4</u>	<u>\$1,200.2</u>

Amounts included in restricted cash primarily represent funds placed in escrow related to litigation and real estate purchases. Restricted cash as of December 31, 2020 also included 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 18 years, some of which include options to extend or terminate the leases.

Operating lease costs for the years ended December 31, 2022, 2021, and 2020 were \$28.8 million, \$29.7 million, and \$30.5 million, respectively. Short-term and variable lease costs were not material for the years ended December 31, 2022, 2021, and 2020.

**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):

	<b>As of December 31,</b>	
	<u>2022</u>	<u>2021</u>
Operating lease right-of-use assets . . . . .	<u>\$92.3</u>	<u>\$92.1</u>
Operating lease liabilities, current portion . . . . .	\$25.5	\$25.5
Operating lease liabilities, long-term portion . . . . .	<u>69.5</u>	<u>69.1</u>
Total operating lease liabilities . . . . .	<u>\$95.0</u>	<u>\$94.6</u>

Maturities of operating lease liabilities at December 31, 2022 were as follows (in millions):

2023 . . . . .	\$ 27.0
2024 . . . . .	18.5
2025 . . . . .	12.5
2026 . . . . .	10.5
2027 . . . . .	8.2
Thereafter . . . . .	<u>26.0</u>
Total lease payments . . . . .	102.7
Less: imputed interest . . . . .	<u>(7.7)</u>
Total lease liabilities . . . . .	<u>\$ 95.0</u>

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

	<b>Years Ended December 31,</b>	
	<u>2022</u>	<u>2021</u>
Weighted-average remaining lease term (in years) . . . . .	6.4	6.2
Weighted-average discount rate . . . . .	1.8%	2.5%

As of December 31, 2022, the Company had additional operating lease commitments of \$14.1 million for office spaces 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, 2022				December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Held-to-maturity</b>								
Bank time deposits . . . . .	\$ 96.0	\$—	\$ —	\$ 96.0	\$ 162.0	\$—	\$ —	\$ 162.0
<b>Available-for-sale</b>								
Bank time deposits . . . . .	\$ —	\$—	\$ —	\$ —	\$ 2.5	\$—	\$ —	\$ 2.5
Commercial paper . . . . .	—	—	—	—	127.7	—	—	127.7
United States								
government and agency securities . . . . .	137.7	—	(6.1)	131.6	147.4	0.6	(0.7)	147.3
Asset-backed securities . . . . .	380.6	—	(14.0)	366.6	515.2	0.3	(2.9)	512.6
Corporate debt securities . . . . .	1,028.1	—	(47.8)	980.3	1,397.1	2.0	(8.3)	1,390.8
Municipal securities . . . . .	2.7	—	(0.2)	2.5	2.8	—	—	2.8
	\$1,549.1	\$—	\$(68.1)	\$1,481.0	\$2,192.7	\$ 2.9	\$(11.9)	\$2,183.7

The cost and fair value of investments in debt securities, by contractual maturity, as of December 31, 2022 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 . . . . .	\$91.5	\$91.5	\$ 362.0	\$ 354.8
Due after 1 year through 5 years . . . . .	4.5	4.5	753.8	710.8
Due after 5 years through 10 years . . . . .	—	—	6.0	5.7
Instruments not due at a single maturity date (a) . . . . .	—	—	427.3	409.7
	\$96.0	\$96.0	\$1,549.1	\$1,481.0

(a) Consists of mortgage- and asset-backed securities.

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)**

The following tables present gross unrealized losses and fair values for those investments that were in an unrealized loss position as of December 31, 2022 and 2021, aggregated by investment category and the length of time that individual securities have been in a continuous loss position (in millions):

	December 31, 2022					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities . . . . .	\$ 61.6	\$(1.5)	\$ 69.5	\$ (4.6)	\$ 131.1	\$ (6.1)
Asset-backed securities . . . . .	103.3	(1.3)	254.6	(12.7)	357.9	(14.0)
Corporate debt securities . . . . .	189.0	(5.3)	784.8	(42.5)	973.8	(47.8)
Municipal securities . . . . .	—	—	2.5	(0.2)	2.5	(0.2)
	<u>\$353.9</u>	<u>\$(8.1)</u>	<u>\$1,111.4</u>	<u>\$(60.0)</u>	<u>\$1,465.3</u>	<u>\$(68.1)</u>

	December 31, 2021					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities . . . . .	\$ 85.1	\$ (0.7)	\$—	\$—	\$ 85.1	\$ (0.7)
Asset-backed securities . . . . .	433.3	(2.9)	—	—	433.3	(2.9)
Corporate debt securities . . . . .	1,114.1	(8.3)	—	—	1,114.1	(8.3)
	<u>\$1,632.5</u>	<u>\$(11.9)</u>	<u>\$—</u>	<u>\$—</u>	<u>\$1,632.5</u>	<u>\$(11.9)</u>

The Company reviews its investments in debt securities to determine if there has been an other-than-temporary decline in fair value. Consideration is given to 1) the length of time and the extent to which the security's fair value has been below cost, 2) the financial condition and near-term prospects of the issuer, including the credit quality of the security's issuer, 3) the Company's intent to sell the security, and 4) whether it is more likely than not the Company will have to sell the security before recovery of its amortized cost. During 2022, the decline in fair value of the debt securities was largely due to changes in interest rates, not credit quality, and as of December 31, 2022, the Company did not intend to sell the securities, and it was not more likely than not that it will be required to sell the securities, before recovery of the unrealized losses, and therefore, the unrealized losses are considered temporary.



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. INVESTMENTS (Continued)**

*Investments in Unconsolidated Entities*

The Company has a number of equity investments in unconsolidated entities. These investments are recorded in “*Long-term Investments*” on the consolidated balance sheets, and are as follows:

	December 31,	
	2022	2021
	(in millions)	
<b>Equity method investments</b>		
Carrying value of equity method investments . . . . .	\$ 21.4	\$ 8.4
<b>Equity securities</b>		
Carrying value of non-marketable equity securities . . . . .	86.9	84.1
<b>Total investments in unconsolidated entities . . . . .</b>	<b>\$108.3</b>	<b>\$92.5</b>

During 2022, the Company made \$13.2 million of equity investments in limited liability companies that invest in qualified community development entities (“CDEs”) through the New Markets Tax Credit (“NMTC”) program. The NMTC program provides federal tax incentives to investors to make investments in distressed communities and promotes economic improvements through the development of successful businesses in these communities. The NMTC is equal to 39% of the qualified investment and is taken over seven years. These limited liability companies are variable interest entities (“VIEs”). The Company determined that it is not the primary beneficiary of the VIEs because it does not have the power to direct the activities that most significantly impact the economic performance of the VIEs, and therefore the Company does not consolidate these entities. Instead, the NMTC investments are accounted for as equity method investments.

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. During 2022, the Company recorded an upward adjustment of \$0.8 million based on observable price changes and a downward adjustment of \$0.5 million due to an impairment. During 2021, the Company recorded an upward adjustment of \$4.2 million based on observable price changes. As of December 31, 2022, the Company had recorded cumulative upward adjustments of \$8.8 million based on observable price changes, and cumulative downward adjustments of \$3.1 million due to impairments and observable price changes.

During 2022, 2021, and 2020, the gross realized gains or losses from sales of available-for-sale investments were not material.

**8. ACQUISITIONS AND OTHER ARRANGEMENTS**

**In-process Research and Development Assets**

The Company acquired Harpoon Medical, Inc (“Harpoon”) on December 1, 2017 and CardiAQ Valve Technologies, Inc. (“CardiAQ”) on July 3, 2015. In-process research and development assets acquired as part of these transactions 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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. ACQUISITIONS AND OTHER ARRANGEMENTS (Continued)**

manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals.

In September 2022, the Company decided to exit the *HARPOON* program and recorded a \$28.1 million impairment charge to fully write off the in-process research and development assets. See Note 4 for further information.

The valuation for CardiAQ 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 2024.

Upon completion of development, the underlying research and development intangible assets will be amortized over their estimated useful lives.

Certain of the Company's business acquisitions involve contingent consideration arrangements. Payment of additional consideration in the future may be required, contingent upon the acquired business reaching certain performance milestones, such as attaining specified sales levels or obtaining regulatory approvals. See Note 11 for further information.

**Investments in Variable Interest Entities**

Edwards has relationships with various variable interest entities that it does not consolidate as Edwards lacks the power to direct the activities that significantly impact the economic success of these entities. The Company's maximum loss exposure to variable interest entities, prior to the exercise of options to acquire the entities, is limited to its investments in the variable interest entities, which include equity investments, options to acquire, and promissory notes.

In August 2022, the Company entered into an option agreement with a medical device company. Under the option agreement, Edwards paid \$47.1 million for an option to acquire the medical device company. The \$47.1 million option is included in "*Other Assets*" on the consolidated balance sheet.

In June 2022, the Company entered into a convertible promissory note and amended its existing warrant agreement with a medical device company. Under the convertible promissory note agreement, the Company has agreed to loan the medical device company up to \$47.5 million, of which \$32.5 million has been advanced as of December 31, 2022. In addition, the Company amended its warrant agreement under which the Company had previously paid \$35.0 million for an option to acquire the medical device company. The amendment extends the warrant right period. The \$35.0 million warrant and the \$32.5 million note receivable are included in "*Other Assets*" on the consolidated balance sheet.

In May 2022, the Company entered into an option agreement with a medical technology company. Under the option agreement, Edwards paid \$60.0 million for an option to acquire the medical technology company, of which \$10 million was paid in 2021. The \$60.0 million option is included in "*Other Assets*" on the consolidated balance sheet.

In April 2021, the Company recorded \$35.9 million, included in "*Long-term Investments*," related to its investment in a privately-held medical device company (the "Investee"), including an initial cash investment in

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. ACQUISITIONS AND OTHER ARRANGEMENTS (Continued)**

the Investee’s preferred equity securities and other consideration. Also, in April 2021, the Company paid \$5.7 million, included in “*Other Assets*,” for an option to acquire the Investee. Per the agreement, the Company may be required to invest up to an additional \$9.9 million in the Investee’s preferred equity securities and up to an additional \$21.8 million for the option to acquire the Investee, depending on the achievement of certain milestones, of which the Company invested \$10.8 million in the fourth quarter of 2021 upon achievement of the first milestone. The Company also agreed to loan the Investee up to \$45.0 million under a secured promissory note. As of December 31, 2022, there had been no borrowings under this secured promissory note.

In addition, Edwards has made equity investments through the NMTC program in limited liability companies that are considered VIEs. For more information, see Note 7.

**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 2022, the Company recorded a \$52.7 million impairment charge related to certain of its developed technology and in-process research and development assets. See Note 4 for further information.

The changes in the carrying amount of goodwill, by segment, during the years ended December 31, 2022 and 2021 were as follows:

	<u>United States</u>	<u>Europe</u>	<u>Rest of World</u>	<u>Total</u>
	(in millions)			
Goodwill at December 31, 2020 . . . . .	\$773.7	\$68.3	\$331.2	\$1,173.2
Currency translation adjustment . . . . .	—	(5.3)	—	(5.3)
Goodwill at December 31, 2021 . . . . .	<u>773.7</u>	<u>63.0</u>	<u>331.2</u>	<u>1,167.9</u>
Currency translation adjustment . . . . .	—	(3.6)	—	(3.6)
Goodwill at December 31, 2022 . . . . .	<u><u>\$773.7</u></u>	<u><u>\$59.4</u></u>	<u><u>\$331.2</u></u>	<u><u>\$1,164.3</u></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,					
		2022			2021		
		Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
<b>Finite-lived intangible assets</b>							
Patents . . . . .	8.8	\$205.5	\$(185.0)	\$ 20.5	\$185.7	\$(184.2)	\$ 1.5
Developed technology . . . . .	12.2	128.1	(57.9)	70.2	153.9	(55.5)	98.4
Other . . . . .	10.0	12.2	(7.7)	4.5	12.4	(6.8)	5.6
	11.3	345.8	(250.6)	95.2	352.0	(246.5)	105.5
<b>Indefinite-lived intangible assets</b>							
In-process research and development . . . . .		190.0	—	190.0	218.1	—	218.1
		<u>\$535.8</u>	<u>\$(250.6)</u>	<u>\$285.2</u>	<u>\$570.1</u>	<u>\$(246.5)</u>	<u>\$323.6</u>

Amortization expense related to other intangible assets for the years ended December 31, 2022, 2021, and 2020 was \$5.7 million, \$7.7 million, and \$5.4 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2023 . . . . .	\$5.6
2024 . . . . .	5.3
2025 . . . . .	4.8
2026 . . . . .	5.8
2027 . . . . .	6.2

**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, 2022 and 2021:

	December 31,			
	2022		2021	
	Amount	Effective Interest Rate	Amount	Effective Interest Rate
	(in millions)		(in millions)	
Fixed-rate 4.3% Notes . . . . .	\$600.0	4.329%	\$600.0	4.329%
Unamortized discount . . . . .	(0.9)		(1.0)	
Unamortized debt issuance costs . . . . .	(2.8)		(3.3)	
Total carrying amount . . . . .	\$596.3		\$595.7	

As of December 31, 2022 and 2021, the fair value of the Notes was \$575.2 million and \$675.4 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.

In July 2022, the Company and certain of its subsidiaries, as borrowers, entered into a new Five-Year Credit Agreement (“the New Credit Agreement”) with the lenders thereto, which provides for a \$750.0 million multi-currency unsecured revolving credit facility and replaces the Company’s prior credit agreement and related revolving credit facility. The New Credit Agreement matures on July 15, 2027. Subject to certain terms and conditions and the agreement of the lenders, the Company may increase the amount available under the New Credit Agreement by up to an additional \$250.0 million in the aggregate and extend the maturity date for an additional year. Borrowings under the New Credit Agreement bear interest at a variable rate based on the Secured Overnight Financing Rate (“SOFR”), plus a spread ranging from 0.785% to 1.3%, depending on the leverage ratio or credit rating, as defined in the agreement. The Company will also pay a facility fee ranging from 0.09% to 0.20%, depending on the Company’s leverage ratio or credit rating, on the entire credit commitment available, whether or not drawn. The facility fee is expensed as incurred. During 2022, under the New Credit Agreement, the spread over SOFR was 0.9% and the facility fee was 0.1%, and under the previous credit agreement, the spread over the London interbank offered rate was 0.9% and the facility fee was 0.1%. Issuance costs of \$2.1 million are being amortized to interest expense over the term of the New Credit Agreement. As of December 31, 2022 and 2021, there were no borrowings outstanding. Amounts outstanding under the New Credit Agreement, if any from time to time, are classified as long-term obligations in accordance with the terms of the agreement. The New Credit Agreement is unsecured and contains various financial and other covenants, including a maximum leverage ratio, as defined in the agreement. The Company was in compliance with all covenants under the New Credit Agreement at December 31, 2022.

The weighted-average interest rate under all debt obligations, including the impact of the cross currency swap contract (see Note 12), was 3.4% at both December 31, 2022 and 2021, respectively.

**11. FAIR VALUE MEASUREMENTS**

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.

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.



**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, 2022 and 2021 (in millions):

<u>December 31, 2022</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Assets</b>				
Cash equivalents . . . . .	\$ 0.4	\$ —	\$ —	\$ 0.4
Available-for-sale investments:				
Corporate debt securities . . . . .	—	980.3	—	980.3
Asset-backed securities . . . . .	—	366.6	—	366.6
United States government and agency securities . . . . .	37.1	94.5	—	131.6
Municipal securities . . . . .	—	2.5	—	2.5
Investments held for deferred compensation plans . .	112.1	—	—	112.1
Derivatives . . . . .	—	65.5	—	65.5
	<u>\$149.6</u>	<u>\$1,509.4</u>	<u>\$ —</u>	<u>\$1,659.0</u>
<b>Liabilities</b>				
Derivatives . . . . .	\$ —	\$ 27.2	\$ —	\$ 27.2
Contingent consideration liabilities . . . . .	—	—	26.2	26.2
Other liability . . . . .	—	—	14.0	14.0
	<u>\$ —</u>	<u>\$ 27.2</u>	<u>\$40.2</u>	<u>\$ 67.4</u>
 <u>December 31, 2021</u>				
<b>Assets</b>				
Cash equivalents . . . . .	\$ 15.2	\$ 30.7	\$ —	\$ 45.9
Available-for-sale investments:				
Bank time deposits . . . . .	—	2.5	—	2.5
Corporate debt securities . . . . .	—	1,390.8	—	1,390.8
Asset-backed securities . . . . .	—	512.6	—	512.6
United States government and agency securities . . . . .	28.4	118.9	—	147.3
Commercial paper . . . . .	—	127.7	—	127.7
Municipal securities . . . . .	—	2.8	—	2.8
Investments held for deferred compensation plans . .	130.7	—	—	130.7
Derivatives . . . . .	—	55.3	—	55.3
	<u>\$174.3</u>	<u>\$2,241.3</u>	<u>\$ —</u>	<u>\$2,415.6</u>
<b>Liabilities</b>				
Derivatives . . . . .	\$ —	\$ 3.9	\$ —	\$ 3.9
Contingent consideration liabilities . . . . .	—	—	62.0	62.0
Other liability . . . . .	—	—	14.0	14.0
	<u>\$ —</u>	<u>\$ 3.9</u>	<u>\$76.0</u>	<u>\$ 79.9</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. FAIR VALUE MEASUREMENTS (Continued)**

*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, United States 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.

*Deferred Compensation Plans*

The Company holds investments in a variety of money market and mutual funds related to its deferred compensation plans. The fair values of these investments 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 the derivative financial instruments 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.

*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 sales 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 as of December 31, 2022 include (1) the discount rate used to present value the projected cash flows (ranging from 3.8% to 12.8%; weighted average of 4.1%), (2) the probability of milestone achievement (ranging from 0% to 50%; weighted average of 39.6%), and (3) the projected payment dates (2026). 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.

**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 and the other liability for the years ended December 31, 2022 and 2021 (in millions):

	<u>Contingent Consideration</u>	<u>Other Liability</u>	<u>Total</u>
Fair value, December 31, 2020 .....	\$ 186.1	\$ —	\$ 186.1
Additions .....	—	14.0	14.0
Changes in fair value .....	<u>(124.1)</u>	<u>—</u>	<u>(124.1)</u>
Fair value, December 31, 2021 .....	\$ 62.0	\$14.0	\$ 76.0
Changes in fair value .....	<u>(35.8)</u>	<u>—</u>	<u>(35.8)</u>
Fair value, December 31, 2022 .....	<u>\$ 26.2</u>	<u>\$14.0</u>	<u>\$ 40.2</u>

The contingent consideration liabilities related to certain of the Company's previous business acquisitions were reduced in 2022 by \$30.9 million due to both the changes in projected probabilities of milestone achievement and the Company's decision during the third quarter of 2022 to exit its *HARPOON* surgical mitral repair system program (see Note 4). The contingent consideration liabilities were reduced in 2021 by \$123.2 million due to changes in the projected probabilities of milestone achievements and the projected timing of cash inflows from product sales.

**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.

	<u>Notional Amount</u>	
	<u>As of December 31,</u>	
	<u>2022</u>	<u>2021</u>
	(in millions)	
Foreign currency forward exchange contracts .....	\$1,678.4	\$1,498.8
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):

	<u>Balance Sheet Location</u>	<u>Fair Value</u>	
		<u>As of December 31,</u>	<u>As of December 31,</u>
		<u>2022</u>	<u>2021</u>
<b><u>Derivatives designated as hedging instruments</u></b>			
<b>Assets</b>			
Foreign currency contracts .....	Other current assets	\$24.9	\$36.2
Cross currency swap contracts .....	Other assets	\$40.6	\$19.1
<b>Liabilities</b>			
Foreign currency contracts .....	Accrued and other liabilities	\$20.7	\$ 3.9
Foreign currency contracts .....	Other liabilities	\$ 6.5	\$ —



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)**

\$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		
		2022	2021	2020
		(in millions)		
<b>Fair value hedges</b>				
Foreign currency contracts . . . . .	Other income, net	\$(3.9)	\$11.6	\$(1.4)
		(in millions)		
<b>Derivatives not designated as hedging instruments</b>				
Foreign currency contracts . . . . .	Other income, net	\$44.0	\$27.4	\$(15.1)

The following tables present 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, 2022		
	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 . . . . .	\$(1,080.4)	\$(1,567.6)	\$ 2.6
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items . . . . .	—	—	5.5
Derivatives designated as hedging instruments . . . . .	—	—	(5.5)
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach . . . . .	—	—	1.6
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income . . . . .	88.4	—	—

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)**

	<b>Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships Twelve Months Ended December 31, 2021</b>		
	<b>Cost of sales</b>	<b>Selling, general, and administrative expenses</b>	<b>Other Income, net</b>
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 . . . . .	\$(1,248.9)	\$(1,493.7)	\$12.7
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items . . . . .	—	—	(9.0)
Derivatives designated as hedging instruments . . . . .	—	—	9.0
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach . . . . .	—	—	2.6
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income . . . . .	(23.0)	(0.6)	—

The Company expects that during 2023 it will reclassify to earnings a \$29.2 million gain currently recorded in “*Accumulated Other Comprehensive Loss*.” For the years ended December 31, 2022, 2021, and 2020, 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**

The Company maintains defined benefit pension plans in Japan and certain European countries.

	<b>Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(in millions)</b>	
<b>Change in projected benefit obligation:</b>		
Beginning of year . . . . .	\$117.9	\$ 126.2
Service cost . . . . .	5.5	6.5
Interest cost . . . . .	0.5	0.4
Participant contributions . . . . .	1.6	1.5
Actuarial gain . . . . .	(22.6)	(6.1)
Benefits paid . . . . .	(0.6)	(2.5)
Plan amendment . . . . .	(0.3)	(0.5)
Settlements and curtailment gain . . . . .	(1.8)	—
Currency exchange rate changes and other . . . . .	(6.1)	(7.6)
End of year . . . . .	<u>\$ 94.1</u>	<u>\$ 117.9</u>
<b>Change in fair value of plan assets:</b>		
Beginning of year . . . . .	\$ 76.9	\$ 73.3
Actual return on plan assets . . . . .	(4.9)	5.8
Employer contributions . . . . .	3.5	3.1
Participant contributions . . . . .	1.6	1.5
Settlements . . . . .	(1.8)	—
Benefits paid . . . . .	(0.6)	(2.5)
Currency exchange rate changes and other . . . . .	(4.1)	(4.3)
End of year . . . . .	<u>\$ 70.6</u>	<u>\$ 76.9</u>
<b>Funded Status</b>		
Projected benefit obligation . . . . .	\$ (94.1)	\$ (117.9)
Plan assets at fair value . . . . .	70.6	76.9
Underfunded status . . . . .	<u>\$ (23.5)</u>	<u>\$ (41.0)</u>
<b>Net amounts recognized on the consolidated balance sheet:</b>		
Other liabilities . . . . .	<u>\$ 23.5</u>	<u>\$ 41.0</u>
Accumulated other comprehensive loss, net of tax:		
Net actuarial gain (loss) . . . . .	\$ 1.5	\$ (16.4)
Net prior service credit . . . . .	5.3	6.0
Deferred income tax (expense) benefit . . . . .	(1.1)	2.4
Total . . . . .	<u>\$ 5.7</u>	<u>\$ (8.0)</u>

The accumulated benefit obligation (“ABO”) for all defined benefit pension plans was \$86.7 million and \$113.3 million as of December 31, 2022 and 2021, respectively. The projected benefit obligation and ABO were in excess of plan assets for all pension plans as of December 31, 2022 and 2021.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**13. EMPLOYEE BENEFIT PLANS (Continued)**

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

	<b>Years Ended December 31,</b>		
	<b><u>2022</u></b>	<b><u>2021</u></b>	<b><u>2020</u></b>
Service cost, net . . . . .	\$ 5.5	\$ 6.5	\$ 6.3
Interest cost . . . . .	0.5	0.4	0.5
Expected return on plan assets . . . . .	(1.5)	(1.1)	(1.0)
Settlements and curtailment gain . . . . .	0.1	—	—
Amortization of actuarial loss . . . . .	0.5	1.7	1.6
Amortization of prior service credit . . . . .	(0.7)	(0.7)	(0.7)
Net periodic pension benefit cost . . . . .	<u>\$ 4.4</u>	<u>\$ 6.8</u>	<u>\$ 6.7</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:

	<b>December 31,</b>	
	<b><u>2022</u></b>	<b><u>2021</u></b>
Discount rate . . . . .	2.5%	0.5%
Rate of compensation increase . . . . .	2.9%	2.6%
Cash balance interest crediting rate . . . . .	1.5%	2.5%
Social securities increase . . . . .	1.8%	1.6%
Pension increase . . . . .	2.2%	1.8%

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

	<b>Years ended December 31,</b>		
	<b><u>2022</u></b>	<b><u>2021</u></b>	<b><u>2020</u></b>
Discount rate . . . . .	0.5%	0.3%	0.5%
Expected return on plan assets . . . . .	2.1%	1.5%	1.5%
Rate of compensation increase . . . . .	2.6%	2.6%	2.7%
Cash balance interest crediting rate . . . . .	1.5%	2.5%	1.5%
Social securities increase . . . . .	1.6%	1.6%	1.6%
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, 2022, by asset category, are as follows:

Equity securities .....	30.7%
Debt securities .....	41.5%
Real estate .....	10.7%
Other .....	<u>17.1%</u>
Total .....	<u>100.0%</u>

The fair values of the Company's defined benefit plan assets at December 31, 2022 and 2021, by asset category, are as follows (in millions):

<u>December 31, 2022</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Asset Category</b>				
Cash .....	\$ 3.6	\$ —	\$ —	\$ 3.6
Equity securities:				
United States equities .....	1.5	—	—	1.5
International equities .....	17.5	—	—	17.5
Debt securities:				
United States government bonds .....	4.4	—	—	4.4
International government bonds .....	25.6	—	—	25.6
Real estate .....	—	7.6	—	7.6
Mortgages .....	—	3.5	—	3.5
Insurance contracts .....	—	—	0.8	0.8
Total plan assets measured at fair value .....	<u>\$52.6</u>	<u>\$11.1</u>	<u>\$ 0.8</u>	\$64.5
Alternative investments measured at net asset value (a) .....				<u>6.1</u>
Total plan assets .....				<u>\$70.6</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**13. EMPLOYEE BENEFIT PLANS (Continued)**

<u>December 31, 2021</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Asset Category</b>				
Cash .....	\$ 5.4	\$ —	\$ —	\$ 5.4
Equity securities:				
United States equities .....	1.6	—	—	1.6
International equities .....	16.3	—	—	16.3
Debt securities:				
United States government bonds .....	6.2	—	—	6.2
International government bonds .....	26.3	—	—	26.3
Real estate .....	—	7.6	—	7.6
Mortgages .....	—	3.5	—	3.5
Insurance contracts .....	—	—	0.9	0.9
Total plan assets .....	<u>\$55.8</u>	<u>\$11.1</u>	<u>\$ 0.9</u>	<u>\$67.8</u>
Alternative investments measured at net asset value (a) .....				<u>9.1</u>
Total plan assets .....				<u>\$76.9</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.

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, 2022 and 2021 (in millions):

	<u>Insurance Contracts</u>
Balance at December 31, 2020 .....	\$ 1.0
Currency exchange rate impact .....	<u>(0.1)</u>
Balance at December 31, 2021 .....	0.9
Actual return on plan assets:	
Relating to assets still held at December 31, 2022 .....	0.2
Purchases, sales and settlements .....	<u>(0.2)</u>
Currency exchange rate impact .....	<u>(0.1)</u>
Balance at December 31, 2022 .....	<u>\$ 0.8</u>

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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**13. EMPLOYEE BENEFIT PLANS (Continued)**

The following benefit payments, which reflect expected future service, as appropriate, at December 31, 2022, are expected to be paid (in millions):

2023	\$ 7.1
2024	5.2
2025	5.3
2026	6.4
2027	7.6
2028-2032	36.4

As of December 31, 2022, expected employer contributions for 2023 are \$2.4 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 \$45.1 million, \$38.6 million, and \$36.6 million in 2022, 2021, and 2020, 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 participant with a return based on investment alternatives selected by the participant. The amount accrued under these nonqualified plans was \$112.6 million and \$130.9 million at December 31, 2022 and 2021, respectively.

**14. COMMON STOCK**

**Treasury Stock**

In May 2021, 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. In July 2022, the Board of Directors approved an additional \$1.5 billion of repurchases of the Company’s common stock under this program, effective July 28, 2022. The repurchase program does not have an expiration date. Stock repurchased under these programs 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 2022, 2021, and 2020, the Company repurchased 20.1 million, 5.8 million, and 3.1 million shares, respectively, at an aggregate cost of \$1,727.1 million, \$512.8 million, and \$625.4 million, respectively, including shares purchased under a Rule 10b5-1 trading plan, 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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. COMMON STOCK (Continued)**

*Accelerated Share Repurchase*

During 2022 and 2021, 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 applicable 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</u>	<u>Value of Shares as % of Contract Value</u>	<u>Settlement Date</u>	<u>Total Shares Received</u>	<u>Average Price per Share</u>
February 2021 . . . . .	\$250.0	2.4	\$ 83.86	80%	March 2021	3.0	\$ 84.51
January 2022 . . . . .	\$250.0	1.9	\$104.87	80%	February 2022	2.3	\$110.31
October 2022 . . . . .	\$750.0	8.3	\$ 72.43	80%	December 2022	10.3	\$ 72.91

The ASR agreements were each 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 contracts indexed to the Company’s common stock met all the applicable criteria for equity classification and, therefore, were not accounted for as a derivative instrument.

**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, typically 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. Under the Program, the number of shares of common stock authorized 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 \$0.3 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.



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. COMMON STOCK (Continued)**

The Company has an employee stock purchase plan for United States employees and a plan for employees outside of the United States (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 15% 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 of 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 50.4 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 United States 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%.

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

***Option Awards***

	<b>Years Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
Risk-free interest rate . . . . .	3.0%	0.8%	0.3%
Expected dividend yield . . . . .	None	None	None
Expected volatility . . . . .	31.4%	33.5%	33.4%
Expected term (years) . . . . .	5.0	5.0	5.0
Fair value, per share . . . . .	\$34.59	\$28.90	\$21.70

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

***ESPP***

	<b>Years Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
Risk-free interest rate . . . . .	0.5%	0.1%	1.3%
Expected dividend yield . . . . .	None	None	None
Expected volatility . . . . .	32.0%	36.6%	33.1%
Expected term (years) . . . . .	0.6	0.6	0.6
Fair value, per share . . . . .	\$28.18	\$23.07	\$16.61

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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. COMMON STOCK (Continued)**

The weighted-average assumptions used to determine the fair value of the market-based restricted stock units during the years ended December 31, 2022, 2021, and 2020 included a risk-free interest rate of 2.9%, 0.4%, and 0.2%, respectively, and an expected volatility rate of 33.9%, 34.4%, and 32.7%, respectively.

Stock option activity during the year ended December 31, 2022 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>
<b>Outstanding as of December 31, 2021</b> .....	12.3	\$ 52.84		
Options granted .....	1.6	104.52		
Options exercised .....	(2.1)	30.47		
Options forfeited .....	<u>(0.2)</u>	82.81		
<b>Outstanding as of December 31, 2022</b> .....	<u>11.6</u>	63.67	3.4 years	\$204.5
<b>Exercisable as of December 31, 2022</b> .....	<u>7.9</u>	51.28	2.5 years	\$197.3
<b>Vested and expected to vest as of December 31, 2022</b> ...	<u>11.1</u>	62.43	3.3 years	\$203.5

The following table summarizes nonvested restricted stock unit activity during the year ended December 31, 2022 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	<u>Shares</u>	<u>Weighted-Average Grant-Date Fair Value</u>
<b>Nonvested as of December 31, 2021</b> .....	2.3	\$ 73.94
Granted (a) .....	0.9	102.26
Vested .....	(1.1)	64.04
Forfeited .....	<u>(0.1)</u>	83.04
<b>Nonvested as of December 31, 2022</b> .....	<u>2.0</u>	92.30

(a) The shares granted include 0.1 million shares of market-based restricted stock units granted during 2022, 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, 2022, 2021, and 2020 were \$264.5 million, \$359.8 million, and \$323.5 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, 2022, 2021, and 2020, the Company received cash from exercises of stock options of \$64.8 million, \$82.2 million, and \$79.2 million, respectively, and tax benefits from exercises of stock options and vesting of restricted stock units of \$56.9 million, \$76.5 million, and \$72.1 million, respectively. The total grant-date fair value of stock options

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. COMMON STOCK (Continued)**

vested during the years ended December 31, 2022, 2021, and 2020 were \$40.4 million, \$36.2 million, and \$34.0 million, respectively.

As of December 31, 2022, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units, market-based restricted stock units, and employee stock purchase plan subscription awards amounted to \$195.1 million, which will be amortized on a straight-line basis over each award's requisite service period. The weighted-average remaining requisite service period is 31 months.

**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, 2022, 2021, and 2020.

	Foreign Currency Translation Adjustments	Unrealized Gain (Loss) on Hedges	Unrealized Gain (Loss) on Available-for-sale Investments  (in millions)	Unrealized Pension (Costs) Credits (a)	Total Accumulated Other Comprehensive Loss
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) . . . . .	3.1	13.8	(1.4)	0.4	15.9
December 31, 2020 . . . . .	(122.4)	(27.7)	8.6	(19.6)	(161.1)
Other comprehensive (loss) income					
before reclassifications . . . . .	(39.2)	66.3	(29.2)	12.8	10.7
Amounts reclassified from					
accumulated other comprehensive					
loss . . . . .	(6.4)	12.0	8.6	1.0	15.2
Deferred income tax (expense)					
benefit . . . . .	(4.5)	(20.9)	5.1	(2.2)	(22.5)
December 31, 2021 . . . . .	(172.5)	29.7	(6.9)	(8.0)	(157.7)
Other comprehensive (loss) income					
before reclassifications . . . . .	(33.9)	75.2	(77.9)	17.3	(19.3)
Amounts reclassified from					
accumulated other comprehensive					
loss . . . . .	(7.0)	(84.5)	18.8	(0.1)	(72.8)
Deferred income tax (expense)					
benefit . . . . .	(5.4)	3.4	0.4	(3.5)	(5.1)
December 31, 2022 . . . . .	<u>\$(218.8)</u>	<u>\$ 23.8</u>	<u>\$(65.6)</u>	<u>\$ 5.7</u>	<u>\$(254.9)</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. ACCUMULATED OTHER COMPREHENSIVE LOSS (Continued)**

(a) For the years ended December 31, 2022, 2021, and 2020, 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>
<b><u>2022</u></b>			
Prior service credit arising during period . . . . .	\$ —	\$(1.1)	\$(1.1)
Amortization of prior service credit . . . . .	<u>(0.7)</u>	<u>0.3</u>	<u>(0.4)</u>
Net prior service cost arising during period . . . . .	(0.7)	(0.8)	(1.5)
Net actuarial gain arising during period . . . . .	<u>17.9</u>	<u>(2.7)</u>	<u>15.2</u>
Unrealized pension credits, net . . . . .	<u>\$17.2</u>	<u>\$(3.5)</u>	<u>\$13.7</u>
<b><u>2021</u></b>			
Prior service credit arising during period . . . . .	\$ 0.1	\$—	\$ 0.1
Amortization of prior service credit . . . . .	<u>(0.7)</u>	<u>0.1</u>	<u>(0.6)</u>
Net prior service cost arising during period . . . . .	(0.6)	0.1	(0.5)
Net actuarial gain arising during period . . . . .	<u>14.4</u>	<u>(2.3)</u>	<u>12.1</u>
Unrealized pension credits, net . . . . .	<u>\$13.8</u>	<u>\$(2.2)</u>	<u>\$11.6</u>
<b><u>2020</u></b>			
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>\$ (4.6)</u>	<u>\$ 0.4</u>	<u>\$(4.2)</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
	2022	2021	
Foreign currency translation adjustments . . . . .	\$ 7.0	\$ 6.4	Other income, net
	(1.7)	(1.6)	Provision for income taxes
	<u>\$ 5.3</u>	<u>\$ 4.8</u>	Net of tax
Gain (loss) on hedges . . . . .	\$ 88.4	\$(23.0)	Cost of sales
	—	(0.6)	Selling, general, and administrative expenses
	(3.9)	11.6	Other income, net
	<u>84.5</u>	<u>(12.0)</u>	Total before tax
	(22.2)	4.6	Provision for income taxes
	<u>\$ 62.3</u>	<u>\$ (7.4)</u>	Net of tax
Gain (loss) on available-for-sale investments . . . . .	\$(18.8)	\$ (8.6)	Other income, net
	4.6	2.1	Provision for income taxes
	<u>\$(14.2)</u>	<u>\$ (6.5)</u>	Net of tax
Amortization of pension adjustments . . . . .	\$ 0.1	\$ (1.0)	Other income, net
	—	0.1	Provision for income taxes
	<u>\$ 0.1</u>	<u>\$ (0.9)</u>	Net of tax

**16. OTHER INCOME, NET**

	Years Ended December 31,		
	2022	2021	2020
	(in millions)		
Foreign exchange losses (gains), net . . . . .	\$ 1.2	\$ (5.0)	\$(12.3)
Gain on insurance settlement . . . . .	(3.8)	—	—
Loss (gain) on investments . . . . .	1.1	(5.8)	(0.6)
Non-service cost components of net periodic pension benefit cost . . . . .	(1.1)	0.3	0.4
Other . . . . .	—	(2.2)	1.0
Total other income, net . . . . .	<u>\$(2.6)</u>	<u>\$(12.7)</u>	<u>\$(11.5)</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 operations in the United States and outside of the United States as follows (in millions):

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
United States .....	\$ 634.4	\$ 610.9	\$151.3
Outside of the United States, including Puerto Rico .....	1,133.0	1,091.1	765.4
	<u>\$1,767.4</u>	<u>\$1,702.0</u>	<u>\$916.7</u>

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

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
<b>Current</b>			
United States:			
Federal .....	\$ 369.1	\$125.2	\$ 23.4
State and local .....	60.6	25.1	48.2
Outside of the United States, including Puerto Rico ...	66.7	92.6	73.9
Current income tax expense .....	<u>\$ 496.4</u>	<u>\$242.9</u>	<u>\$145.5</u>
<b>Deferred</b>			
United States:			
Federal .....	\$(187.7)	\$ (9.4)	\$ 11.0
State and local .....	(58.9)	(25.4)	(32.9)
Outside of the United States, including Puerto Rico ...	(4.3)	(9.2)	(30.3)
Deferred income tax benefit .....	<u>(250.9)</u>	<u>(44.0)</u>	<u>(52.2)</u>
<b>Total income tax provision</b> .....	<u>\$ 245.5</u>	<u>\$198.9</u>	<u>\$ 93.3</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):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Deferred tax assets</b>		
Capitalized research and development expenses <sup>(a)</sup> . . . .	\$ 199.7	\$ —
Compensation and benefits . . . . .	100.6	109.8
Benefits from uncertain tax positions . . . . .	42.1	33.9
Net tax credit carryforwards . . . . .	160.8	142.0
Net operating loss carryforwards . . . . .	71.7	69.4
Accrued liabilities . . . . .	93.7	108.0
Inventories . . . . .	11.9	13.5
Cash flow and net investment hedges . . . . .	6.6	—
State income taxes . . . . .	0.3	0.4
Investments . . . . .	0.6	0.7
Lease liability obligations . . . . .	6.7	6.6
Other . . . . .	1.9	1.3
Total deferred tax assets . . . . .	<u>696.6</u>	<u>485.6</u>
<b>Deferred tax liabilities</b>		
Property, plant, and equipment . . . . .	(80.2)	(64.1)
Cash flow and net investment hedges . . . . .	—	(6.4)
Deferred tax on foreign earnings . . . . .	(19.2)	(26.3)
Right-of-use assets . . . . .	(6.0)	(6.1)
Other intangible assets . . . . .	(19.9)	(75.5)
Other . . . . .	(2.9)	(2.6)
Total deferred tax liabilities . . . . .	<u>(128.2)</u>	<u>(181.0)</u>
<b>Valuation allowance</b> . . . . .	<u>(99.1)</u>	<u>(82.5)</u>
<b>Net deferred tax assets</b> . . . . .	<u>\$ 469.3</u>	<u>\$ 222.1</u>

(a) As required by the 2017 Tax Cuts and Jobs Act, effective January 1, 2022, the Company's research and development expenditures were capitalized and amortized which resulted in substantially higher cash paid for taxes in 2022 with an equal amount of deferred tax benefits.

During 2022, net deferred tax assets increased \$247.2 million, including items that were recorded to stockholders' equity and which did not impact the Company's income tax provision.

The valuation allowance of \$99.1 million as of December 31, 2022 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, 2022 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 . . . . .	\$ 8.6	\$ 1.8	\$ —	\$ 1.8	2033-2037
United States federal net operating losses . . . . .	11.3	2.4	—	2.4	Indefinite
United States state net operating losses . . . . .	35.7	1.8	(1.7)	0.1	2026-2041
United States state net operating losses . . . . .	2.6	0.1	(0.1)	—	Indefinite
Non-United States net operating losses . . . . .	390.5	65.5	(50.6)	14.9	Indefinite
United States capital losses . . . . .	33.4	0.1	(0.1)	—	2024
Total . . . . .	<u>\$482.1</u>	<u>\$71.7</u>	<u>\$(52.5)</u>	<u>\$19.2</u>	

Certain tax attributes are subject to an annual limitation as a result of the acquisition of CASMED, 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, 2022 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 . . . . .	\$189.8	\$ —	\$189.8	Indefinite
Federal research expenditure tax credits . . . . .	1.3	—	1.3	2026-2039
Foreign tax and general business credits . . . . .	4.3	(3.8)	0.5	2030-2032
Puerto Rico purchases credits . . . . .	26.4	(26.4)	—	Indefinite
Total . . . . .	<u>\$221.8</u>	<u>\$(30.2)</u>	<u>\$191.6</u>	

The Company has \$189.8 million of gross 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 into the distant future. Accordingly, no valuation allowance has been provided. The Company has \$26.4 million of Puerto Rico purchases credits. Throughout its history and into the future, the Company's 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 currently have an indefinite life, the Company continues to record a valuation allowance on the purchases credits carryforwards. The Company recently renegotiated its tax grant under Puerto Rico Act 52-2022 ("Act 52") effective January 1, 2023. Among other items, Act 52 introduced new requirements and limitations on the availability and claiming of tax credits. As a result, the Company now expects that its purchases credits may begin to expire after 2026.

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 United States 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. The Company elected to pay the repatriation tax in installments over eight years.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

The Company asserts that \$1.0 billion of its foreign earnings continue to be indefinitely reinvested and it intends to repatriate \$580.8 million of its foreign earnings as of December 31, 2022. The estimated net tax liability on the indefinitely reinvested earnings if repatriated is \$14.9 million.

The Company has received tax incentives in certain non-United States tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were \$247.4 million (\$0.40 per diluted share), \$208.0 million (\$0.33 per diluted share), and \$189.2 million (\$0.30 per diluted share) for the years ended December 31, 2022, 2021, and 2020, 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):

	<u>Years Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Income tax expense at United States federal statutory rate . . . . .	\$ 371.1	\$ 357.4	\$192.5
Foreign income taxed at different rates . . . . .	(123.9)	(122.2)	(80.5)
State and local taxes, net of federal tax benefit . . . . .	21.1	11.9	5.0
Tax credits, federal and state . . . . .	(50.0)	(48.4)	(43.1)
Build of reserve for prior years' uncertain tax positions . . . . .	11.6	3.6	4.2
Tax on global intangible low-taxed income . . . . .	61.4	56.5	49.2
Foreign-derived intangible income deduction . . . . .	(15.0)	(1.3)	(2.6)
Contingent consideration liabilities . . . . .	(7.5)	(26.1)	2.9
United States federal deductible employee share-based compensation . . . . .	(31.6)	(47.8)	(48.3)
Nondeductible employee share-based compensation . . . . .	5.8	5.3	4.2
Other . . . . .	2.5	10.0	9.8
Income tax provision . . . . .	<u>\$ 245.5</u>	<u>\$ 198.9</u>	<u>\$ 93.3</u>

The Company's effective tax rate for 2022 increased in comparison to 2021 primarily due to the decrease in the tax benefit from the change in fair value of contingent consideration liabilities and the decrease in the excess tax benefit from employee share-based compensation. The Company's effective tax rate for 2021 increased in comparison to 2020 primarily due to the tax benefit from the Settlement Agreement with Abbott in 2020 (see Note 3) and the decrease in the excess tax benefit from employee share-based compensation, partially offset by the tax benefit from the change in fair value of contingent consideration liabilities.

Uncertain Tax Positions

As of December 31, 2022 and 2021, the gross uncertain tax positions were \$475.3 million and \$358.4 million, respectively. The Company estimates that these liabilities would be reduced by \$182.1 million and \$135.1 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 \$293.2 million and \$223.3 million, respectively, if not required, would favorably affect the Company's effective tax rate.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

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,		
	2022	2021	2020
Uncertain gross tax positions, January 1 . . . . .	\$358.4	\$281.8	\$203.1
Current year tax positions . . . . .	120.6	82.1	86.4
Increase in prior year tax positions . . . . .	3.8	2.3	6.0
Decrease in prior year tax positions . . . . .	(0.6)	(4.8)	(10.0)
Settlements . . . . .	(0.4)	(0.3)	(3.7)
Lapse of statutes of limitations . . . . .	(6.5)	(2.7)	—
Uncertain gross tax positions, December 31 . . . . .	\$475.3	\$358.4	\$281.8

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, 2022, the Company had accrued \$29.1 million (net of \$15.4 million tax benefit) of interest related to uncertain tax positions, and as of December 31, 2021, the Company had accrued \$19.5 million (net of \$8.1 million tax benefit) of interest related to uncertain tax positions. During 2022, 2021, and 2020, the Company recognized interest expense, net of tax benefit, of \$9.6 million, \$5.2 million, and \$5.0 million, respectively, in “*Provision for Income Taxes*” on the consolidated statements of operations.

In the normal course of business, the Internal Revenue Service (“IRS”) and other taxing authorities are in different stages of examining various years of the Company’s tax filings. During these audits, the Company may receive proposed audit adjustments that could be material. Therefore, there is a possibility that an adverse outcome in these audits could have a material effect on the Company’s results of operations and financial condition. 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 for any adjustments that may result from these uncertain tax positions.

At December 31, 2022, 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 India for years from 2010 and on.

The Company executed an Advance Pricing Agreement (“APA”) in 2018 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 (collectively “Surgical/TAVR”) intercompany royalty transactions, then reverted to IRS

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

examination for further consideration as part of the respective years' regular tax audits. In addition, the Company executed other bilateral 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 all of the APAs which cover transactions with Japan for the years 2020 and forward. An APA between Switzerland and Japan covering tax years 2020 through 2024 was executed in 2021. The execution of the other APA renewals depends on many variables outside of the Company's control.

The audits of the Company's United States federal income tax returns through 2014 have been closed. The IRS audit field work for the 2015 through 2017 tax years was completed during the second quarter of 2021, except for transfer pricing and related matters. The IRS began its examination of the 2018 through 2020 tax years during the first quarter of 2022.

During 2021, the Company received a Notice of Proposed Adjustment ("NOPA") from the IRS for the 2015-2017 tax years relating to transfer pricing involving certain Surgical/TAVR intercompany royalty transactions between the Company's United States and Switzerland subsidiaries. The NOPA proposes an increase to the Company's United States taxable income, which could result in additional tax expense for this period of approximately \$210 million and represents a significant change to previously agreed upon transfer pricing methodologies for these types of transactions. The Company has formally disagreed with the NOPA and submitted a formal protest on the matter during the fourth quarter of 2021. During the second quarter of 2022, the Company received the IRS's rebuttal to its protest and was notified that the case has been transferred to the IRS Independent Office of Appeals. The opening conference is scheduled for the first quarter of 2023. The Company continues to evaluate all possible remedies available to it, which could take several years to resolve. The Company believes the amounts previously accrued related to this uncertain tax position are sufficient and, accordingly, has not accrued any additional amount based on the NOPA received. While no payment of any amount related to the NOPA is required to be made, if at all, until all applicable proceedings have been completed, the Company made an advance payment of tax in November 2022 to prevent the further accrual of interest on any potential deficiency.

Certain Surgical/TAVR intercompany royalty transactions covering tax years 2015 through 2022 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, 2022. The Company has considered this information, as well as information regarding the NOPA and rebuttal described above, in its evaluation of its uncertain tax positions. The impact of 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 in its existing uncertain tax positions may occur in the next 12 months and, therefore, has continued to record the uncertain tax positions as a long-term liability.

**18. LEGAL PROCEEDINGS**

The Company is reviewing and investigating whether business activities in Japan and other markets violate certain provisions of the Foreign Corrupt Practices Act ("FCPA"). The Company voluntarily notified the SEC and the United States Department of Justice ("DOJ") during 2021 that it has engaged outside counsel to conduct this review and investigation. The Company has provided status updates to the SEC and DOJ since that time. Any determination that the Company's operations or activities are not in compliance with existing laws, including the FCPA, could result in the imposition of fines, penalties, and equitable remedies. The Company cannot currently predict the outcome of the review and investigation or the potential impact on its financial statements.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**18. LEGAL PROCEEDINGS (Continued)**

On September 28, 2021, Aortic Innovations LLC, a non-practicing entity, filed a lawsuit against Edwards Lifesciences Corporation and certain of its subsidiaries (“Edwards”) in the United States District Court for the District of Delaware alleging that Edwards’ *SAPIEN 3 Ultra* product infringes certain of its patents. The Company is unable to predict the ultimate outcome of this matter or estimate a range of possible exposure; therefore, no amounts have been accrued. The Company intends to vigorously defend itself in this litigation.

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 “Lawsuits”). The 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 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 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 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 sanctions are involved is \$1 million.

**19. SEGMENT INFORMATION**

Edwards Lifesciences 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 the same as those described in Note 2. Segment net sales and segment operating income are based on internally derived foreign exchange rates 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. There were no customers that represented 10% or more of the Company’s total net sales.

Certain items are maintained at the corporate level and are not allocated to the segments. The non-allocated items include net interest income, 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



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**19. SEGMENT INFORMATION (Continued)**

impractical to determine the amount of depreciation expense included in each segment, and, therefore, a portion 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):

	<b>Years Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
<b>Segment Net Sales</b>			
United States . . . . .	\$3,132.6	\$2,963.1	\$2,516.8
Europe . . . . .	1,213.7	1,099.6	945.2
Japan . . . . .	559.3	528.0	448.6
Rest of World . . . . .	610.7	533.2	451.5
Total segment net sales . . . . .	<u>\$5,516.3</u>	<u>\$5,123.9</u>	<u>\$4,362.1</u>
<b>Segment Operating Income</b>			
United States . . . . .	\$2,130.9	\$2,051.0	\$1,727.3
Europe . . . . .	652.2	569.1	479.3
Japan . . . . .	376.7	348.0	286.4
Rest of World . . . . .	247.7	185.2	150.1
Total segment operating income . . . . .	<u>\$3,407.5</u>	<u>\$3,153.3</u>	<u>\$2,643.1</u>

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

	<b>Years Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
<b>Net Sales Reconciliation</b>			
Segment net sales . . . . .	\$ 5,516.3	\$ 5,123.9	\$ 4,362.1
Foreign currency . . . . .	(133.9)	108.6	24.2
Consolidated net sales . . . . .	<u>\$ 5,382.4</u>	<u>\$ 5,232.5</u>	<u>\$ 4,386.3</u>
<b>Pre-tax Income Reconciliation</b>			
Segment operating income . . . . .	\$ 3,407.5	\$ 3,153.3	\$ 2,643.1
Unallocated amounts:			
Corporate items . . . . .	(1,714.1)	(1,613.8)	(1,358.0)
Special charge . . . . .	(60.7)	—	—
Intellectual property litigation expenses, net . . .	(15.8)	(20.6)	(405.4)
Change in fair value of contingent consideration liabilities, net . . . . .	35.8	124.1	(13.6)
Foreign currency . . . . .	95.8	47.3	31.5
Consolidated operating income . . . . .	<u>1,748.5</u>	<u>1,690.3</u>	<u>897.6</u>
Non-operating income . . . . .	18.9	11.7	19.1
Consolidated pre-tax income . . . . .	<u>\$ 1,767.4</u>	<u>\$ 1,702.0</u>	<u>\$ 916.7</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**19. SEGMENT INFORMATION (Continued)**

**Enterprise-Wide Information**

(in millions)

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,		
	2022	2021	2020
<b>Net Sales by Geographic Area</b>			
United States .....	\$3,132.6	\$2,963.1	\$2,516.8
Europe .....	1,174.8	1,190.3	973.6
Japan .....	473.6	528.9	460.1
Rest of World .....	601.4	550.2	435.8
	<u>\$5,382.4</u>	<u>\$5,232.5</u>	<u>\$4,386.3</u>
<b>Net Sales by Major Product Area</b>			
Transcatheter Aortic Valve Replacement .....	\$3,518.2	\$3,422.5	\$2,857.3
Transcatheter Mitral and Tricuspid Therapies .....	116.1	86.0	41.8
Surgical Structural Heart .....	893.1	889.1	761.8
Critical Care .....	855.0	834.9	725.4
	<u>\$5,382.4</u>	<u>\$5,232.5</u>	<u>\$4,386.3</u>
<b>Long-lived Tangible Assets by Geographic Area</b>			
United States .....	\$1,188.5	\$1,195.8	\$1,084.3
Europe .....	191.8	197.9	192.7
Japan .....	13.2	19.7	20.4
Rest of World .....	331.6	335.5	311.0
	<u>\$1,725.1</u>	<u>\$1,748.9</u>	<u>\$1,608.4</u>

**20. 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, 2022					
Allowance for credit losses (a) .....	\$15.7	\$ 0.9	\$ 0.1	\$(5.0)	\$11.7
Tax valuation allowance (b) .....	82.5	3.0	14.2	(0.6)	99.1
Year ended December 31, 2021					
Allowance for credit losses (a) .....	\$16.4	\$ 1.2	\$ 0.6	\$(2.5)	\$15.7
Tax valuation allowance (b) .....	71.6	12.4	—	(1.5)	82.5
Year ended December 31, 2020					
Allowance for credit losses (a) .....	\$14.7	\$ 3.1	\$ —	\$(1.4)	\$16.4
Tax valuation allowance (b) .....	65.8	6.3	0.6	(1.1)	71.6

(a) The deductions related to allowances for credit losses represent accounts receivable which are written off.

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**20. VALUATION AND QUALIFYING ACCOUNTS (Continued)**

- (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.

**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) or 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2022.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded as of December 31, 2022 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, 2022. The effectiveness of the Company's internal control over financial reporting as of December 31, 2022 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 2022 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other Information**

None.

**Item 9C. Information Regarding Foreign Jurisdictions That Prevent Inspections**

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 2023 Annual Meeting of Stockholders (the “Proxy Statement”) (which Proxy Statement will be filed with the SEC within 120 days of December 31, 2022). 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 <https://ir.edwards.com> under “Governance & Sustainability—Corporate Responsibility & Sustainability—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 “Board of Directors Matters—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 July 15, 2021 (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences’ report on Form 8-K filed on July 15, 2021)
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 (incorporated by reference to Exhibit 4.2 in Edwards Lifesciences’ report on Form 10-K for the fiscal year ended December 31, 2022)
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	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”)
4.5	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 July 15, 2022, among Edwards Lifesciences Corporation and certain of its subsidiaries, as Borrowers, the lenders signatory thereto, Bank of America, N.A., as Administrative Agent (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences’ report on Form 8-K filed on July 21, 2022)
#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)
*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)



Exhibit No.	Description
*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	Description of Severance Benefits for Mr. Jean-Luc Lemercier (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2021)
*10.8	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)
*10.9	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)
*10.10	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)
*10.11	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 10.11 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*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 10.12 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*10.13	Edwards Lifesciences Corporation Form of Long-Term Stock Incentive Compensation Program Global Performance-Based Restricted Stock Unit Award Agreement for awards granted beginning May 2015 (incorporated by reference to Exhibit 10.13 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*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 Exhibit 10.15 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*10.16	Edwards Lifesciences Corporation Form of Participant Stock Option Statement and related Nonemployee Directors Stock Incentive Program Nonqualified Stock Option Award Agreement (incorporated by reference to Exhibit 10.16 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)

Exhibit No.	Description
*10.17	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Units Agreement (incorporated by reference to Exhibit 10.17 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*10.18	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Agreement (incorporated by reference to Exhibit 10.18 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2022)
*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 13, 2023

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 13, 2023
<u>                    /s/ SCOTT B. ULLEM                    </u> Scott B. Ullem	Corporate Vice President, Chief Financial Officer (Principal Financial Officer)	February 13, 2023
<u>                    /s/ ROBERT W.A. SELLERS                    </u> Robert W.A. Sellers	Senior Vice President, Corporate Controller (Principal Accounting Officer)	February 13, 2023
<u>                    /s/ KIERAN T. GALLAHUE                    </u> Kieran T. Gallahue	Director	February 13, 2023
<u>                    /s/ LESLIE S. HEISZ                    </u> Leslie S. Heisz	Director	February 13, 2023
<u>                    /s/ PAUL A. LAVIOLETTE                    </u> Paul A. LaViolette	Director	February 13, 2023
<u>                    /s/ STEVEN R. LORANGER                    </u> Steven R. Loranger	Director	February 13, 2023
<u>                    /s/ MARTHA H. MARSH                    </u> Martha H. Marsh	Director	February 13, 2023
<u>                    /s/ RAMONA SEQUEIRA                    </u> Ramona Sequeira	Director	February 13, 2023
<u>                    /s/ NICHOLAS J. VALERIANI                    </u> Nicholas J. Valeriani	Director	February 13, 2023

**Exhibit 21.1**

The following is a list of subsidiaries of Edwards Lifesciences Corporation, omitting subsidiaries which, considered in the aggregate as a single subsidiary, would not constitute a significant subsidiary as of December 31, 2022:

<u>Legal Entity</u>	<u>State of Incorporation/ Formation</u>	<u>Country of Incorporation/ Formation</u>
Edwards Lifesciences LLC .....	Delaware	U.S.
Edwards Lifesciences (U.S.) Inc. ....	Delaware	U.S.
Edwards Lifesciences (Japan) Limited .....		Japan

**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, 333-217909, 333-255853, and 333-255854) and Form S-3 (No. 333-266272) of Edwards Lifesciences Corporation of our report dated February 13, 2023 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 13, 2023





**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 13, 2023

**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, 2022 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.

February 13, 2023

/s/ MICHAEL A. MUSSALLEM

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

February 13, 2023

/s/ SCOTT B. ULLEM

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

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# 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 Annual Meeting of Stockholders will be held on May 11, 2023 at 10:00 am (Pacific) at the offices of Edwards Lifesciences Corporation.

## 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 website – [ir.edwards.com](http://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](mailto: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](http://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

**Steven R. Loranger**  
Former Chairman, President  
& Chief Executive Officer,  
ITT Corporation

**Martha H. Marsh**  
Former President &  
Chief Executive Officer,  
Stanford Hospital & Clinics

**Ramona Sequeira**  
President,  
Global Portfolio Division,  
Takeda Pharmaceutical USA, Inc.

**Nicholas J. Valeriani**  
Former Chief Executive Officer,  
West Health Institute

## Executive Management

**Michael A. Mussallem**  
Chairman & Chief Executive Officer

**Donald E. Bobo, Jr.**  
Corporate Vice President,  
Strategy & Corporate Development

**Todd J. Brinton, M.D., F.A.C.C.**  
Corporate Vice President,  
Advanced Technology  
Chief Scientific Officer

**Daveen Chopra**  
Corporate Vice President,  
Transcatheter Mitral  
& Tricuspid Therapies

**Dirksen J. Lehman**  
Corporate Vice President,  
Public Affairs

**Jean-Luc Lemerrier**  
Corporate Vice President,  
EMEA, Canada, Latin America  
& JAPAC

**Christine Z. McCauley**  
Corporate Vice President,  
Human Resources

**Joseph Nuzzolese**  
Corporate Vice President,  
Global Supply Chain & Quality

**Arnold A. Pinkston**  
Corporate Vice President,  
General Counsel

**Gary I. Sorsher**  
Senior Vice President  
Quality & Regulatory Compliance

**Katie M. Szyman**  
Corporate Vice President,  
Critical Care

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

**Larry L. Wood**  
Corporate Vice President &  
Group President, Transcatheter  
Aortic Valve Replacement &  
Surgical Structural Heart

**Bernard J. Zovighian**  
President





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](http://www.newheartvalve.com) or [www.edwards.com](http://www.edwards.com). For the full important safety information, please see [www.ir.edwards.com/annuals-and-proxies](http://www.ir.edwards.com/annuals-and-proxies)

**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.

Edwards EVOQUE Tricuspid Valve Replacement / Edwards Cardioband System / PASCAL 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 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 present 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.

## Trademarks

Edwards, Edwards Lifesciences, the stylized E logo, 1-800-4-A-HEART, Acumen, Acumen IQ, Alterra, Cardioband, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, Edwards SAPIEN M3, Every Heartbeat Matters, EVOQUE, EVOQUE EOS FloTrac, ForeSight, HemoSphere, Hypotension Prediction Index, INSPIRIS, INSPIRIS RESILIA, KONECT, KONECT RESILIA, MITRIS RESILIA, Life is Now, PARTNER, PARTNER 3, PASCAL, PASCAL Ace, RESILIA, SAPIEN, SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN M3 are all trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

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