

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.

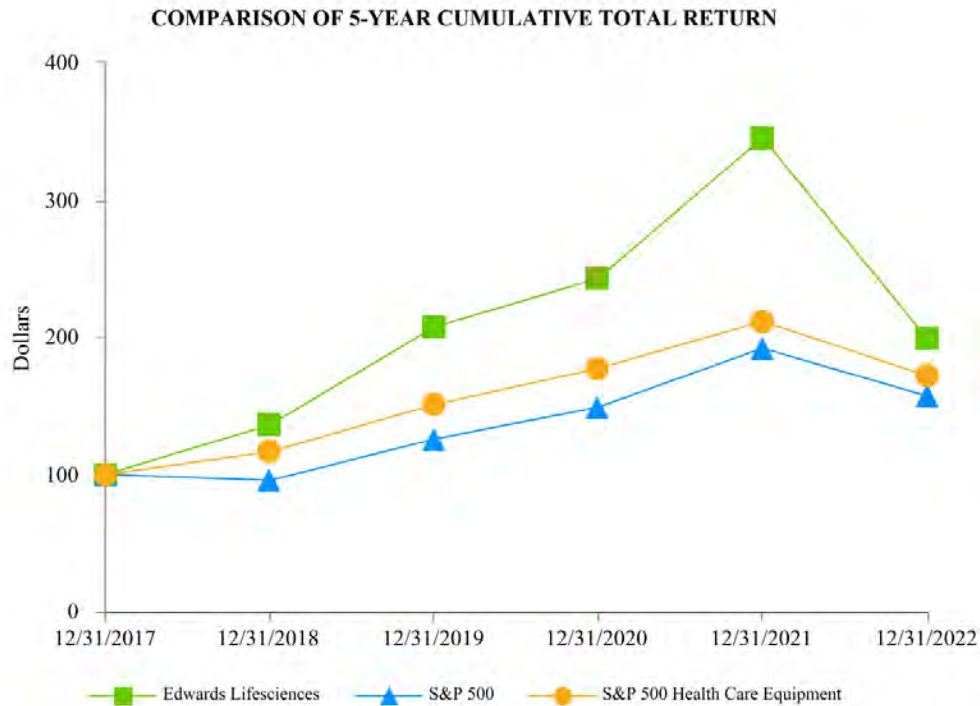
Issuer Purchases of Equity Securities

Period	Total Number of Shares (or Units) Purchased (a)	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions) (b)
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	11,669,472	74.18	11,669,179	

- (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.



	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

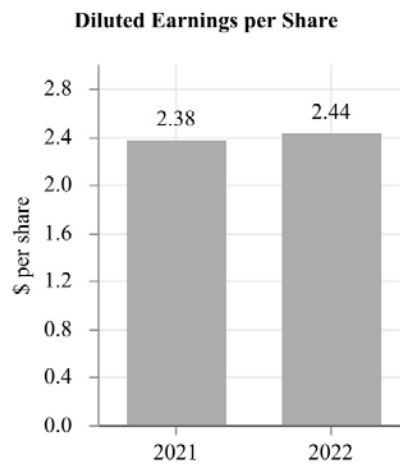
Item 6. [Reserved]

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)

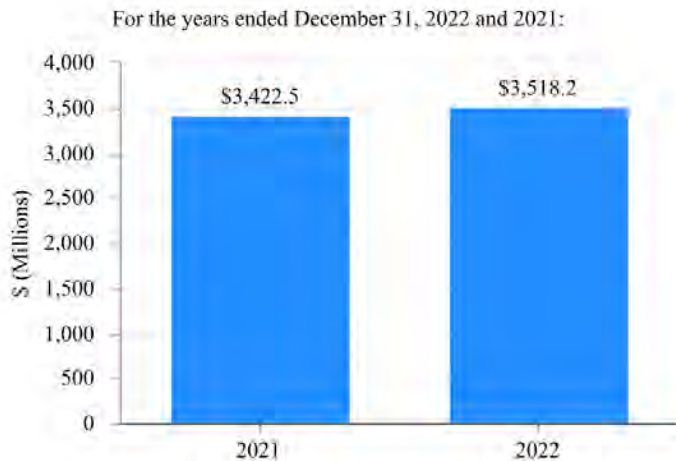
	Years Ended December 31,		Change	
	2022	2021	\$	%
United States	\$ 3,132.6	\$ 2,963.1	\$ 169.5	5.7 %
Europe	1,174.8	1,190.3	(15.5)	(1.3)%
Japan	473.6	528.9	(55.3)	(10.4)%
Rest of World	601.4	550.2	51.2	9.3 %
Outside of the United States	2,249.8	2,269.4	(19.6)	(0.9)%
Total net sales	\$ 5,382.4	\$ 5,232.5	\$ 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



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

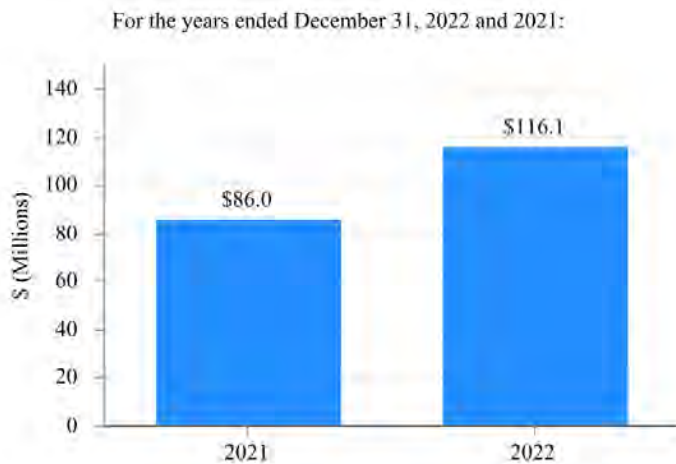
- higher sales of the *Edwards SAPIEN* platform in 2022, primarily the *Edwards SAPIEN 3 Ultra* valve in the United States, Europe, and Rest of World, the *Edwards SAPIEN 3 Ultra RESILIA* valve in the United States, and the *Edwards SAPIEN 3* in Japan;

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.

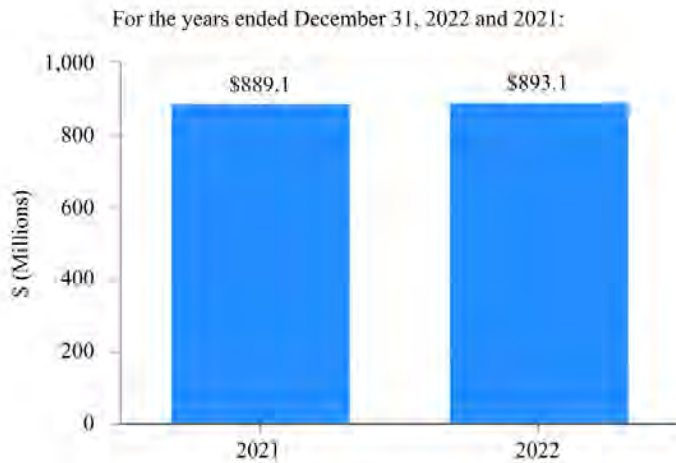
Transcatheter Mitral and Tricuspid Therapies



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.

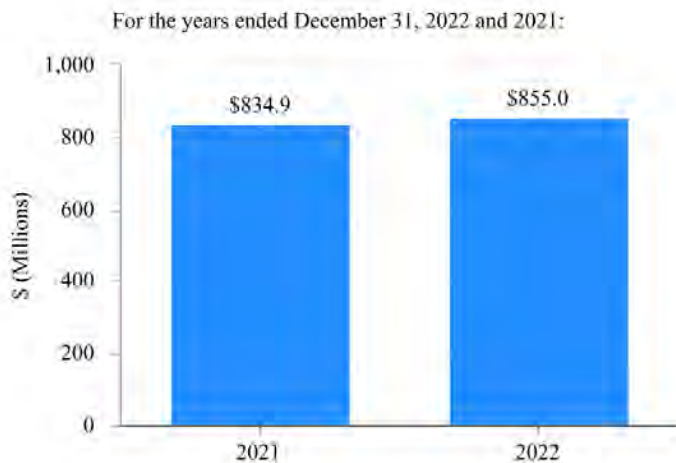
Surgical Structural Heart



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



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



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).

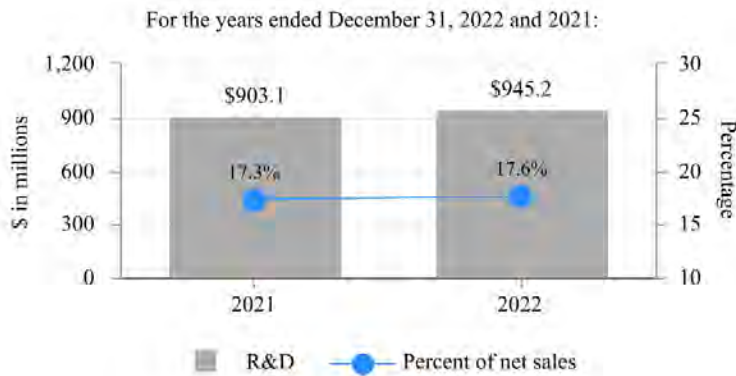
Selling, General, and Administrative ("SG&A") Expenses



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



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)

	Years Ended December 31,	
	2022	2021
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	—	(2.2)
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)

	Years Ended December 31,		Change	
	2022	2021	\$	%
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*."

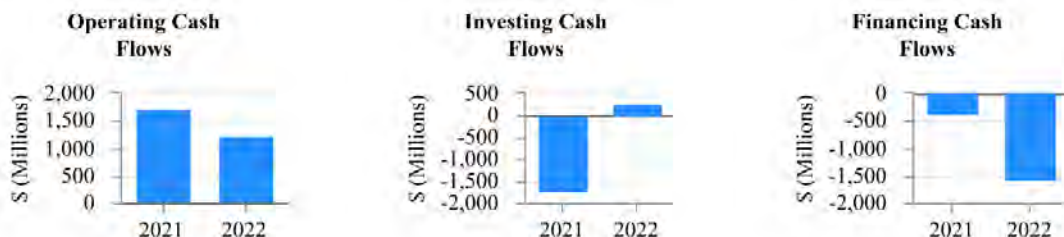
From time to time, we repurchase shares of our common stock under share repurchase programs authorized by the Board of Directors. We consider several factors in determining when to execute share repurchases, including, among other things, expected dilution from stock plans, cash capacity, and the market 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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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
ASSETS		
Current assets		
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
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
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)		
Stockholders' equity (Note 14)		
Preferred stock, \$0.01 par value, authorized 50.0 shares, no shares outstanding	—	—
Common stock, \$1.00 par value, 1,050.0 shares authorized, 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>
Share information (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
Cash flows from operating activities			
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	1,218.2	1,732.1	1,054.3
Cash flows from investing activities			
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	252.3	(1,722.5)	(531.1)
Cash flows from financing activities			
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	(1,584.5)	(356.3)	(486.9)
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	\$ 772.6	\$ 867.4	\$ 1,200.2

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

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in millions)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Par Value	Shares	Amount				
BALANCE AT DECEMBER 31, 2019	218.1	\$ 218.1	9.0	\$ (1,278.7)	\$ 1,623.3	\$ 3,741.6	\$ (156.0)	\$ 4,148.3
Net income						823.4		823.4
Other comprehensive loss, net of tax							(5.1)	(5.1)
Common stock issued under equity plans	4.5	4.5			136.0			140.5
Stock-based compensation expense					92.6			92.6
Purchases of treasury stock			3.1	(625.4)				(625.4)
Stock issued to effect stock split	413.8	413.8			(413.8)			—
BALANCE AT DECEMBER 31, 2020	636.4	636.4	12.1	(1,904.1)	1,438.1	4,565.0	(161.1)	4,574.3
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)
BALANCE AT DECEMBER 31, 2021	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)
BALANCE AT DECEMBER 31, 2022	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 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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

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*."

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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*."

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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Income Taxes

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

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

	Years Ended December 31,		
	2022	2021	2020
Basic:			
Net income	\$ 1,521.9	\$ 1,503.1	\$ 823.4
Weighted-average shares outstanding	619.0	623.3	622.6
Basic earnings per share	\$ 2.46	\$ 2.41	\$ 1.32
Diluted:			
Net income	\$ 1,521.9	\$ 1,503.1	\$ 823.4
Weighted-average shares outstanding	619.0	623.3	622.6
Dilutive effect of stock plans	5.2	7.9	9.3
Dilutive weighted-average shares outstanding	624.2	631.2	631.9
Diluted earnings per share	\$ 2.44	\$ 2.38	\$ 1.30

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,

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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):

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

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 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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

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:

	As of December 31,	
	2022	2021
	(in millions)	
Inventories		
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>
Property, plant, and equipment, net		
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
	<u>2,383.2</u>	<u>2,201.2</u>
Accumulated depreciation	<u>(750.4)</u>	<u>(654.6)</u>
	<u>\$ 1,632.8</u>	<u>\$ 1,546.6</u>
Accrued and other liabilities		
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)

	Years Ended December 31,		
	2022	2021	2020
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)

	Years Ended December 31,		
	2022	2021	2020
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	\$ 772.6	\$ 867.4	\$ 1,200.2

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.

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

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

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. LEASES (Continued)

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		26.0
Total lease payments		102.7
Less: imputed interest		(7.7)
Total lease liabilities	\$	95.0

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

	Years Ended December 31,	
	2022	2021
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.

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
<u>Held-to-maturity</u>								
Bank time deposits	\$ 96.0	\$ —	\$ —	\$ 96.0	\$ 162.0	\$ —	\$ —	\$ 162.0
<u>Available-for-sale</u>								
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

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. INVESTMENTS (Continued)

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
	<u>\$ 96.0</u>	<u>\$ 96.0</u>	<u>\$ 1,549.1</u>	<u>\$ 1,481.0</u>

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

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

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)	
Equity method investments		
Carrying value of equity method investments	\$ 21.4	\$ 8.4
Equity securities		
Carrying value of non-marketable equity securities	86.9	84.1
Total investments in unconsolidated entities	<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 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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS AND OTHER ARRANGEMENTS (Continued)

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 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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)

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:

	United States	Europe	Rest of World	Total
	(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	773.7	63.0	331.2	1,167.9
Currency translation adjustment	—	(3.6)	—	(3.6)
Goodwill at December 31, 2022	<u>\$ 773.7</u>	<u>\$ 59.4</u>	<u>\$ 331.2</u>	<u>\$ 1,164.3</u>

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
Finite-lived intangible assets							
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
Indefinite-lived intangible assets							
In-process research and development		190.0	—	190.0	218.1	—	218.1
		\$ 535.8	\$ (250.6)	\$ 285.2	\$ 570.1	\$ (246.5)	\$ 323.6

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 (in millions)	Effective Interest Rate	Amount (in millions)	Effective Interest Rate
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	<u>\$ 596.3</u>		<u>\$ 595.7</u>	

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.

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

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

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

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

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>	Level 1	Level 2	Level 3	Total
Assets				
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>
Liabilities				
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>				
Assets				
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>
Liabilities				
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>

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

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

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.

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):

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

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.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

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

	Notional Amount	
	As of December 31,	
	2022	2021
	(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):

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

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

				Gross Amounts Not Offset in the Consolidated Balance Sheet			
				Financial Instruments	Cash Collateral Received	Net Amount	
December 31, 2022	Gross Amounts	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts Presented in the Consolidated Balance Sheet				
Derivative Assets							
Foreign currency contracts	\$ 24.9	\$ —	\$ 24.9	\$ (12.0)	\$ —	\$ 12.9	
Cross currency swap contracts	\$ 40.6	\$ —	\$ 40.6	\$ —	\$ —	\$ 40.6	
Derivative Liabilities							
Foreign currency contracts	\$ 27.2	\$ —	\$ 27.2	\$ (12.0)	\$ —	\$ 15.2	
December 31, 2021							
Derivative Assets							
Foreign currency contracts	\$ 36.2	\$ —	\$ 36.2	\$ (2.8)	\$ —	\$ 33.4	
Cross currency swap contracts	\$ 19.1	\$ —	\$ 19.1	\$ —	\$ —	\$ 19.1	
Derivative Liabilities							
Foreign currency contracts	\$ 3.9	\$ —	\$ 3.9	\$ (2.8)	\$ —	\$ 1.1	

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

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)					
Cash flow hedges									
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)					
Net investment hedges									
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 \$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)		
Fair value hedges				
Foreign currency contracts	Other income, net	\$ (3.9)	\$ 11.6	\$ (1.4)
	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)		
Derivatives not designated as hedging instruments				
Foreign currency contracts	Other income, net	\$ 44.0	\$ 27.4	\$ (15.1)

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

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	—	—

	Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships		
	Twelve Months Ended December 31, 2021		
	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	\$ (1,248.9)	\$ (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.

	Years Ended December 31,	
	2022	2021
	(in millions)	
Change in projected benefit obligation:		
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>
Change in fair value of plan assets:		
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>
Funded Status		
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>
Net amounts recognized on the consolidated balance sheet:		
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):

	Years Ended December 31,		
	2022	2021	2020
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	\$ 4.4	\$ 6.8	\$ 6.7

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

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

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

	December 31,	
	2022	2021
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:

	Years ended December 31,		
	2022	2021	2020
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	17.1 %
Total	100.0 %

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):

December 31, 2022	Level 1	Level 2	Level 3	Total
Asset Category				
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	\$ 52.6	\$ 11.1	\$ 0.8	\$ 64.5
Alternative investments measured at net asset value (a)				6.1
Total plan assets				\$ 70.6

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

<u>December 31, 2021</u>	Level 1	Level 2	Level 3	Total
Asset Category				
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)				9.1
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):

	Insurance Contracts
Balance at December 31, 2020	\$ 1.0
Currency exchange rate impact	(0.1)
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	(0.2)
Currency exchange rate impact	(0.1)
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):

Agreement Date	Initial Delivery				Final Settlement		
	Amount Paid	Shares Received	Price per Share	Value of Shares as % of Contract Value	Settlement Date	Total Shares Received	Average Price per Share
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.

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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. COMMON STOCK (Continued)

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

	Years Ended December 31,		
	2022	2021	2020
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

	Years Ended December 31,		
	2022	2021	2020
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. 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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. COMMON STOCK (Continued)

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):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	12.3	\$ 52.84		
Options granted	1.6	104.52		
Options exercised	(2.1)	30.47		
Options forfeited	(0.2)	82.81		
Outstanding as of December 31, 2022	11.6	63.67	3.4 years	\$ 204.5
Exercisable as of December 31, 2022	7.9	51.28	2.5 years	\$ 197.3
Vested and expected to vest as of December 31, 2022	11.1	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):

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

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. ACCUMULATED OTHER COMPREHENSIVE LOSS

Presented below is a summary of activity for each component of "Accumulated Other Comprehensive Loss" for the years ended December 31, 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):

	Pre-Tax Amount	Tax (Expense) Benefit	Net of Tax Amount
2022			
Prior service credit arising during period	\$ —	\$ (1.1)	\$ (1.1)
Amortization of prior service credit	(0.7)	0.3	(0.4)
Net prior service cost arising during period	(0.7)	(0.8)	(1.5)
Net actuarial gain arising during period	17.9	(2.7)	15.2
Unrealized pension credits, net	\$ 17.2	\$ (3.5)	\$ 13.7
2021			
Prior service credit arising during period	\$ 0.1	\$ —	\$ 0.1
Amortization of prior service credit	(0.7)	0.1	(0.6)
Net prior service cost arising during period	(0.6)	0.1	(0.5)
Net actuarial gain arising during period	14.4	(2.3)	12.1
Unrealized pension credits, net	\$ 13.8	\$ (2.2)	\$ 11.6
2020			
Prior service credit arising during period	\$ 0.6	\$ (0.2)	\$ 0.4
Amortization of prior service credit	(0.7)	0.1	(0.6)
Net prior service cost arising during period	(0.1)	(0.1)	(0.2)
Net actuarial loss arising during period	(4.5)	0.5	(4.0)
Unrealized pension costs, net	\$ (4.6)	\$ 0.4	\$ (4.2)

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
	\$ 5.3	\$ 4.8	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
	84.5	(12.0)	Total before tax
	(22.2)	4.6	Provision for income taxes
	\$ 62.3	\$ (7.4)	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
	\$ (14.2)	\$ (6.5)	Net of tax
Amortization of pension adjustments	\$ 0.1	\$ (1.0)	Other income, net
	—	0.1	Provision for income taxes
	\$ 0.1	\$ (0.9)	Net of tax

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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>

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):

	Years Ended December 31,		
	2022	2021	2020
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):

	Years Ended December 31,		
	2022	2021	2020
Current			
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>
Deferred			
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>
Total income tax provision	<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):

	December 31,	
	2022	2021
Deferred tax assets		
Capitalized research and development expenses ^(a)	\$ 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	696.6	485.6
Deferred tax liabilities		
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	(128.2)	(181.0)
Valuation allowance	(99.1)	(82.5)
Net deferred tax assets	<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):

	Carryforward Amount	Tax Benefit Amount	Valuation Allowance	Net Tax Benefit	Carryforward Period Ends
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	\$ 482.1	\$ 71.7	\$ (52.5)	\$ 19.2	

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):

	Carryforward Amount	Valuation Allowance	Net Tax Benefit	Carryforward Period Ends
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	\$ 221.8	\$ (30.2)	\$ 191.6	

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.

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),

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

\$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):

	Years Ended December 31,		
	2022	2021	2020
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.

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	<u>\$ 475.3</u>	<u>\$ 358.4</u>	<u>\$ 281.8</u>

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

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 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

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

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.

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.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. SEGMENT INFORMATION (Continued)

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 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):

	Years Ended December 31,		
	2022	2021	2020
Segment Net Sales			
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>
Segment Operating Income			
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):

	Years Ended December 31,		
	2022	2021	2020
Net Sales Reconciliation			
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>
Pre-tax Income Reconciliation			
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
Net Sales by Geographic Area			
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>
Net Sales by Major Product Area			
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>
Long-lived Tangible Assets by Geographic Area			
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>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

20. VALUATION AND QUALIFYING ACCOUNTS

			Additions				
	Balance at Beginning of Period		Charged to Costs and Expenses	Charged to Other Accounts		Deductions	Balance at End of Period

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

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

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.

Exhibit No.	Description
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)
*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)

Exhibit No.	Description
*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)
*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.

February 13, 2023

EDWARDS LIFESCIENCES CORPORATION

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:

Legal Entity		State of Incorporation/ Formation		Country of Incorporation/ Formation
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

Exhibit 31.1

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

I, Michael A. Mussallem, 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/ MICHAEL A. MUSSALLEM

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

February 13, 2023

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*

EXHIBIT 56

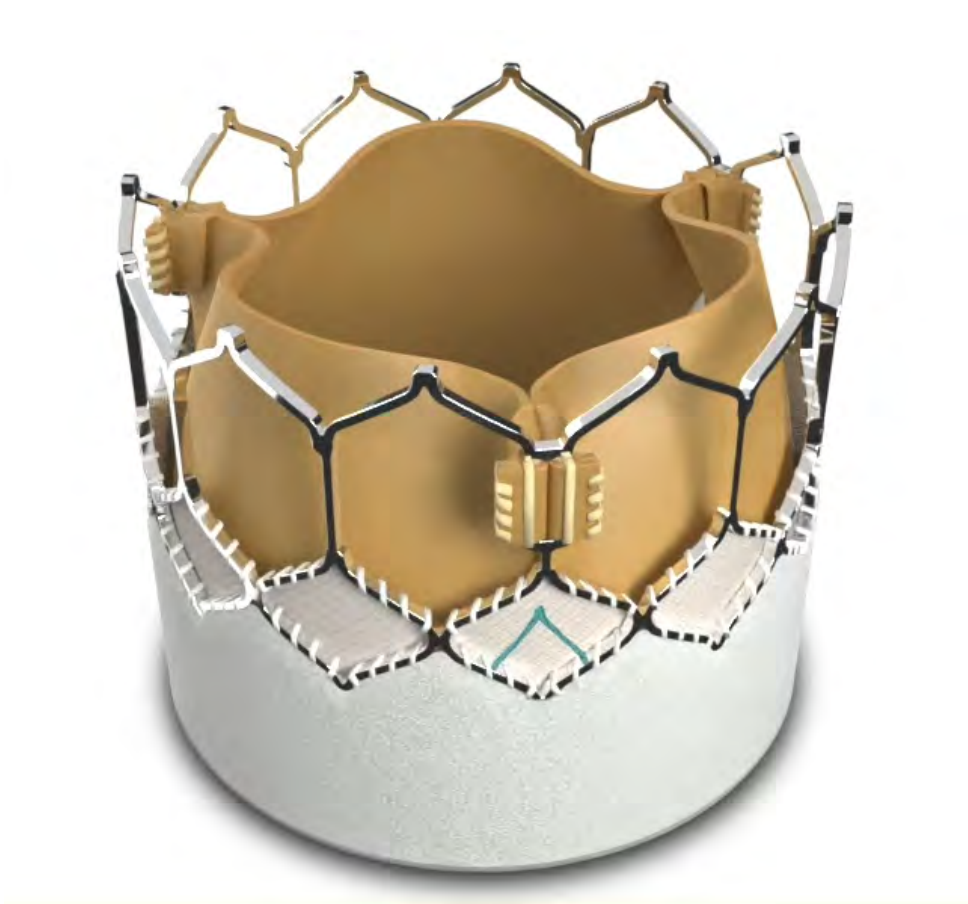


The SAPIEN 3 Ultra Valve, Now Powered By RESILIA Tissue

[Home](#) > [Heart Team](#) > [Devices](#) > [TAVR](#) > [SAPIEN 3 Ultra RESILIA](#)

Building on the benefits of the SAPIEN 3 platform, now with RESILIA tissue's calcium-blocking technology*²

Calcification is a leading cause of structural valve deterioration (SVD) in aortic tissue valves.¹ RESILIA tissue effectively addresses calcification with advanced calcium-blocking.*²



Stable capping blocks calcium from binding to tissue*

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

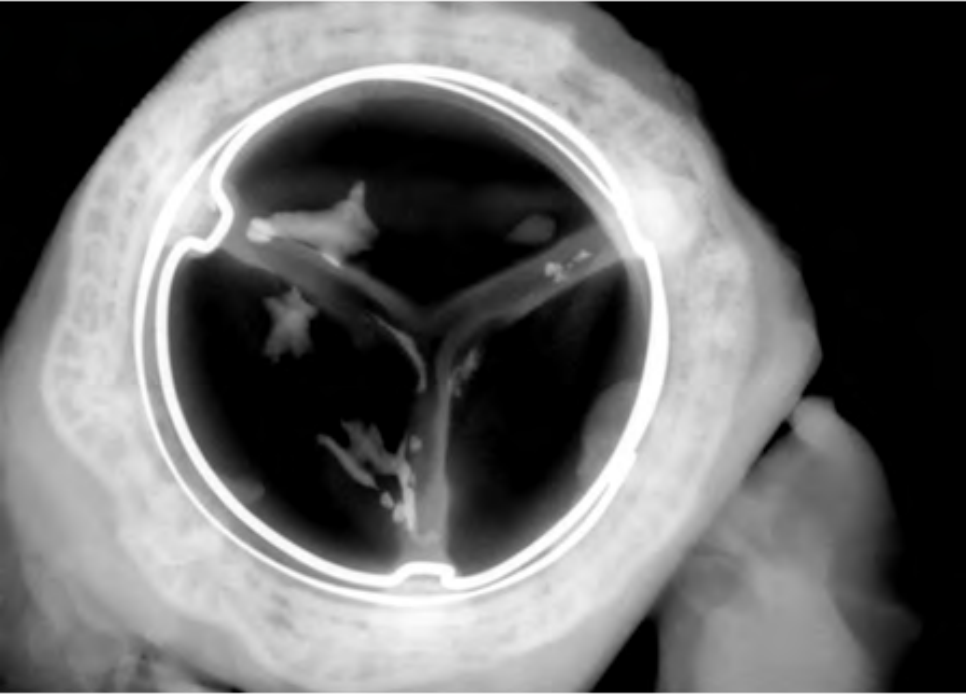
See the difference

Important Safety Information

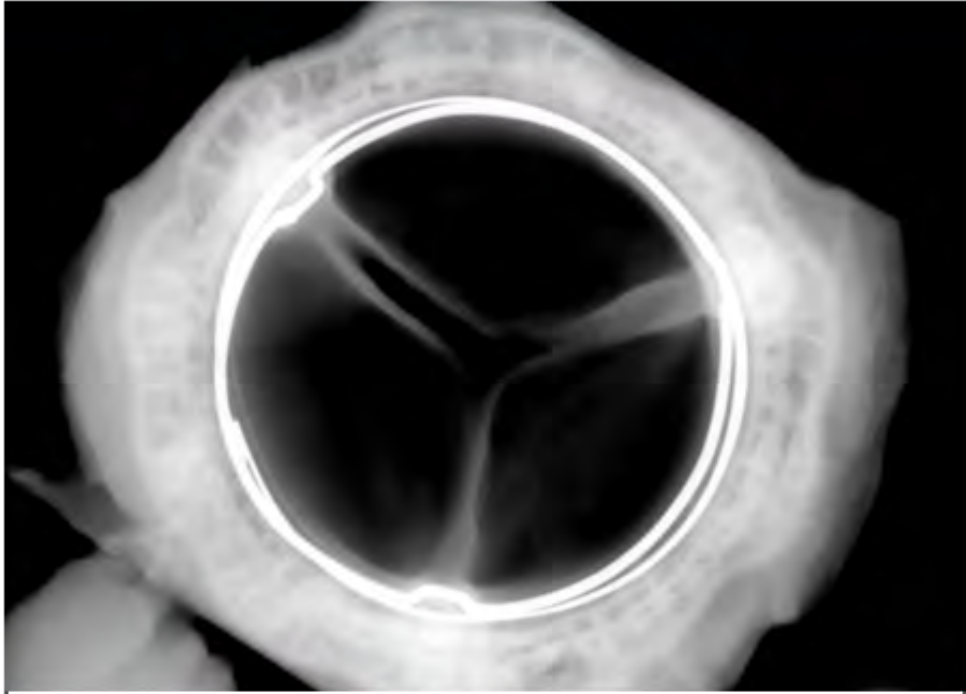
Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in

Control Valve (6900P)



RESILIA Tissue Valve



72% lower calcium content^{†2}

RESILIA tissue features the same tissue technology used in the #1 implanted surgical valve in the U.S.

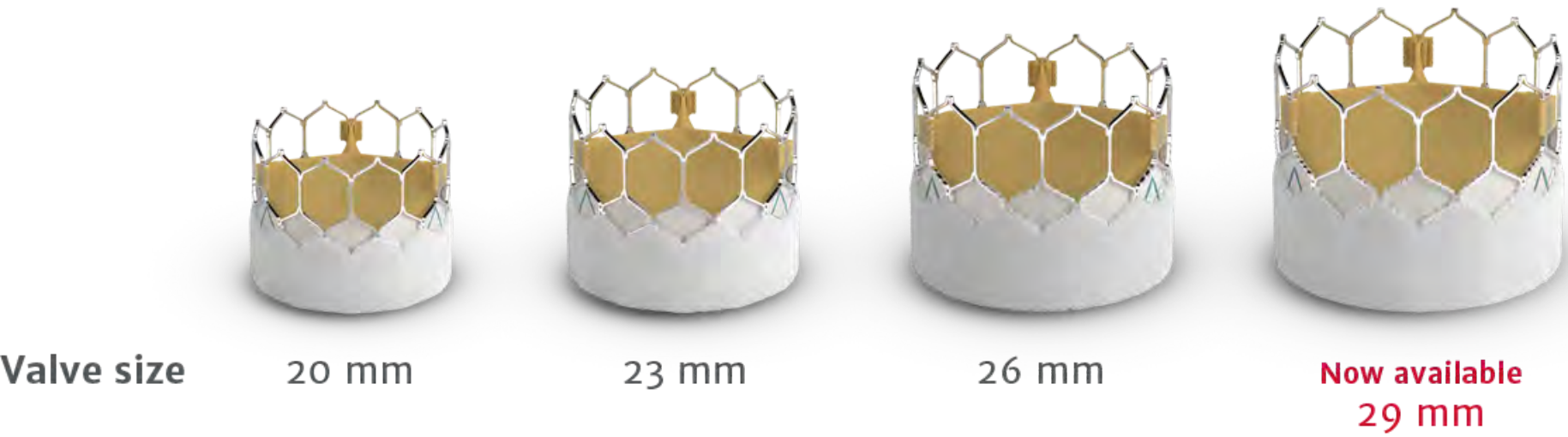
Delivering the potential to improve valve longevity and reduce reintervention^{*†}

^{*}No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.
[†]RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards in a juvenile sheep model. Flameng, et al. *J Thorac Cardiovasc Surg* 2015;149:340-5.



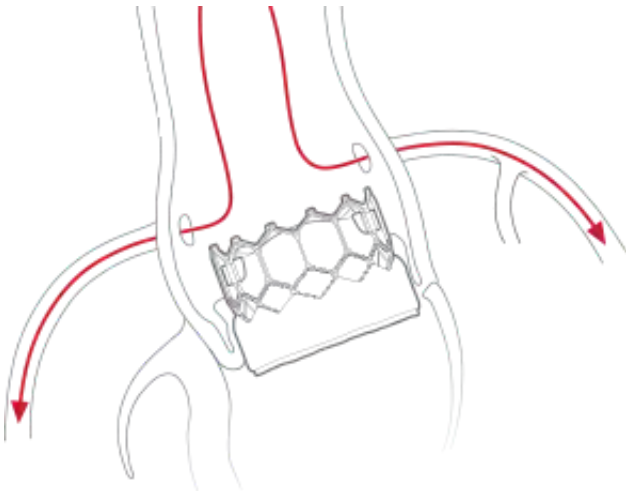
The only transcatheter heart valve (THV) with dry tissue storage

SAPIEN 3 Ultra valve taller* paravalvular leak (PVL) skirt now available in the 29 mm size



*Compared to SAPIEN 3 valve

The SAPIEN 3 TAVR fully addresses the vital considerations for lifetime management



Superior outcomes†4	Future treatment options
1% death and disabling stroke at one year 4 90.9% none/trace PVL at discharge 5 6.5% new pacemaker rate at 30 days 4	100% successful post-TAVR coronary access rate (68/68 patients)6 The only transcatheter heart valve with a THV-in-THV indication

†In the PARTNER 3 trial, SAPIEN 3 TAVR was proven superior to surgery on the primary endpoint of all-cause death, all stroke, and reshospitalization (valve-related or procedure-related, and including due to heart failure) at one year and multiple prespecified secondary endpoints in low risk patients.

Click a hot spot to learn more

technology*

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

In a robust clinical trial, surgical valves with RESILIA tissue demonstrated 0% structural valve deterioration (SVD) at 5 years.*3

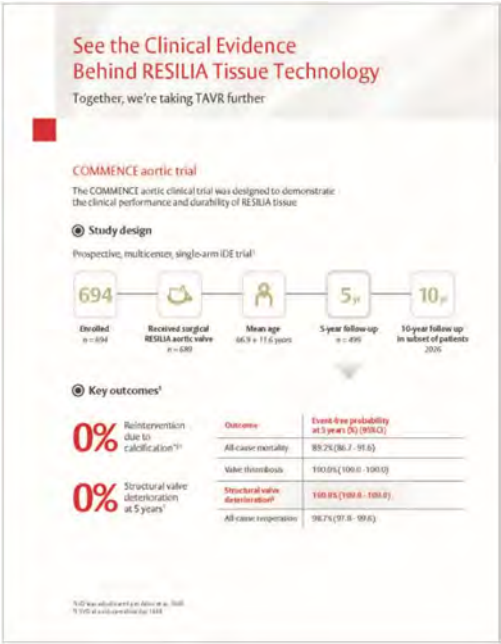
0%

SVD at 5 years*

0%

reintervention due to calcification

*SVD measured per surgical guidelines as any reintervention



Download Clinical Data

See the clinical evidence behind RESILIA tissue technology.

Download now

Important Safety Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in

Register for updates →

Be the first to receive the latest news in transcatheter heart valves, including event announcements.

References: 1. Schoen F, et al. Calcification of Tissue Heart Valve Substitutes: Progress Towards Understanding and Prevention. *Ann Thorac Surg* 2005 79;1072–80 2. Flameng W, Hermans H, Verbeken E, et al: Randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg*. 2015;149(1):340–345. 3. Bavaria JE, Griffith B, Heimansohn DA, et al. Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with RESILIA tissue [published online ahead of print, 2022 Jan 20]. *Ann Thorac Surg*. 2022;S0003–4975(22)00063–7. doi:10.1016/j.athoracsur.2021.12.058. 4. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic–valve replacement with a balloon–expandable valve in low–risk patients. *NEJM*. 2019; 380:1695–1705. doi:10.1056/NEJMoa1814052. 5. Nazif TM, Cahill TJ, Daniels D, et al. Real–world experience with the SAPIEN 3 Ultra transcatheter heart valve: a propensity–matched analysis from the United States. *Circ Cardiovasc Interv*. 2021;14:e010543. doi:10.1161/CIRCINTERVENTIONS.121.010543. 6. Tarantini G, Nai Fovino L, Le Prince P, et al. Coronary access and percutaneous coronary intervention up to 3 years after transcatheter aortic valve implantation with a balloon–expandable valve. *Circ Cardiovasc Interv*. 2020;13:e008972. doi:10.1161/CIRCINTERVENTIONS.120.008972.



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EXHIBIT 57



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Premarket Approval (PMA)



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[CFR Title 21](#)¹⁶ | [Radiation-Emitting Products](#)¹⁷ | [X-Ray Assembler](#)¹⁸ | [Medsun Reports](#)¹⁹ | [CLIA](#)²⁰ | [TPLC](#)²¹

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Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the [original PMA](#)²³ record for more information.

Device	Edwards Commander Delivery System
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered
	EDWARDS LIFESCIENCES, LLC.
Applicant	One Edwards Way
	Irvine, CA 92614
PMA Number	P140031
Supplement Number	S148
Date Received	10/04/2022
Decision Date	10/24/2022
Product Code	NPT ²⁴
Advisory Committee	Cardiovascular
Supplement Type	30-Day Notice
Supplement Reason	Process Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No
Approval Order Statement	Implementation Of Commander Delivery System Flex Shaft Subassembly Manufacturing At The Edwards Draper, UT Facility.

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Page Last Updated: 02/06/2023

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Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

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EXHIBIT 58



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Premarket Approval (PMA)



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[CFR Title 21](#)¹⁶ | [Radiation-Emitting Products](#)¹⁷ | [X-Ray Assembler](#)¹⁸ | [Medsun Reports](#)¹⁹ | [CLIA](#)²⁰ | [TPLC](#)²¹

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Device	Crimper
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered EDWARDS LIFESCIENCES, LLC.
Applicant	One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S150
Date Received	11/14/2022
Decision Date	12/12/2022
Product Code	NPT ²⁴
Advisory Committee	Cardiovascular
Supplement Type	30-Day Notice
Supplement Reason	Process Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No
Approval Order Statement	Implement In-House Injection Molding Processes For Crimper Subassemblies.

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EXHIBIT 59



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Premarket Approval (PMA)



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Device	Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered EDWARDS LIFESCIENCES, LLC.
Applicant	One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S151
Date Received	01/05/2023
Decision Date	01/20/2023
Product Code	NPT ²⁴
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track No User Fee
Supplement Reason	Location Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No
Approval Order Statement	Approval For A Manufacturing Site Located At 35 Changi North Crescent, Changi South East, SG 499641 (Edwards Lifesciences Singapore Pte Ltd.) For RESILIA Tissue Processing.

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EXHIBIT 60

**Edwards Lifescience Corporation
Investor Day
December 8, 2022**

Presenters

Mark Wilterding, Senior Vice President Investor Relations, Treasurer
Michael Mussallem, Chairman and Chief Executive Officer
Larry Wood, Corporate Vice President, Transcatheter Aortic Valve Replacement
Bernard Zovighian, Corporate Vice President, Transcatheter Mitral and Tricuspid Therapies
Daveen Chopra, Corporate Vice President, Surgical Structural Heart
Katie Szyman, Corporate Vice President, Critical Care
Scott Ullem, Corporate Vice President, Chief Financial Officer –

Q&A Participants

Robbie Marcus – J.P. Morgan
Larry Biegelsen – Wells Fargo
Vijay Kumar – Evercore
Joanne Winch – Unknown
Pito Chickering – Deutsche Bank
Travis – Unknown
Josh Jennings – Cowen
Chris Pasquale – Nephron
Rick Wise – Stifel
Adam Maeder – Piper Sandler
Matt Miksic – Barclays
Anthony Petrone – CFA
Rich Neuter – Truist Securities
Bill Plovanic – Canaccord
Cecilia Furlong – Morgan Stanley
Matt Taylor – Jefferies
Ed – Unknown

Mark Wilterding

Good afternoon, everybody. Welcome to the Edwards Lifesciences 2022 Investor Conference. I'm Mark Wilterding, Senior Vice President of Investor Relations and the Treasurer at Edwards. And on behalf of everyone here from the company, we're really glad you could make it. And thank you for taking time out to spend with us here today.

I've got a couple of housekeeping items I wanted to mention up front and get out of the way. One, we issued a couple of press releases this morning. So to the extent you haven't seen them, I would urge you to take a look. They walk through the succession plan that we announced, as well as some of the key messages you'll hear out of today's event. Secondly, for those of you who aren't here in the room today, the slides are available on our website at ir.edwards.com.

You're able to access the entirety of the book. You can follow along online, and I think you'll find that helpful.

The third point I'd want to mention is that as you look at the agenda, you'll see that we've allotted some time for Q&A, and so we'll have the management team up on stage together for about an hour. When we get into that portion of the presentation, please just raise your hand. We'll call on you. Limit your questions to one and we'll try to get to as many as possible in the hour that we have. If you wouldn't mind advancing. I don't have a clicker. I apologize. I've got two quick slides I want to run by you.

One is the forward looking statements. We'll be making some forward looking statements as we typically do. They are--excuse me. Thank you. Familiarize yourself with this slide. They're available on our website as well as on file with the SEC. We'll also be referring to non-GAAP financials. We think this helps make year-over-year comparisons a little bit easier. Again, the reconciliations from GAAP to non-GAAP available on our website to the extent you need them.

I love working at Edwards. In fact, one of the best parts about working at Edwards I think is our patient focus culture. It means a lot to me. I know it means a lot to the team. I talked to a lot of you about it. But I think the best way to really show it is by way of a video. So we're going to run this and then we'll get the show started. Thank you.

(VIDEO BEGINS)

Unknown Speaker

The patient experience gives the employees here at Edwards the opportunity to engage with patients one-on-one.

Unknown Speaker

it is our flagship listening event, which is so important to our employees and the future of our company.

Unknown Speaker

We have our critical care patient. It's (INAUDIBLE) from Las Vegas, Nevada. Next up, (INAUDIBLE).

Unknown Speaker

I'm not just a patient. I am a recognizable known person to these people.

Unknown Speaker

It seems like I have a big family here that I didn't even know about.

Unknown Speaker

What happens here when patients come to campus is magical.

Unknown Speaker

This is Cynthia Gonzalez.

Unknown Speaker

Patients get to come and actually spend time and meet the people that design their products and built their products that have impacted their lives.

Unknown Speaker

Thanks. You're wonderful, wonderful. They said I would meet the person. They said like one person who made my valve, but I'm meeting the whole crew.

Unknown Speaker

The patient experience allows us to really learn from them to better improve their care overall.

Unknown Speaker

I kind of retreated from my family, took a step back because I didn't think I was going to be here. I've been given a second chance, and I'm not going to throw it away. Yeah. So.

Unknown Speaker

I play volleyball at Ohio State. So this valve allowed me to keep living out my dream. So I'm very thankful for all of you.

Unknown Speaker

I was speechless. It kind of emboldened me in the work that we're doing.

Unknown Speaker

It brings to life, really, these projects that we tinker with on a day-to-day basis, will eventually serve people in a meaningful way.

Unknown Speaker

The juice that I get from the patient experience and from today is just keep going because someone out there is depending on you.

Unknown Speaker

All of this lets us know that it's worth it, but also motivates us to push the envelope further (INAUDIBLE) and to get there faster.

Unknown Speaker

Now when I wake up, I'm going to have that spark in me that each of these projects that I'm working on is going to help patients in the end.

Unknown Speaker

I can't wait until tomorrow, can't wait to do more good work for future patients

(VIDEO ENDS)

Michael Mussallem

All right. Welcome, everybody. I'll share my thoughts and so happy that you're with us. Gives you a nice little view into our company and how we feel about things. I hope you enjoy this environment here. Being in this iconic location is something that's kind of fun and reminds us of the importance of what we do and what a great history that we all got a chance to participate in.

So I'm going to get in, and I'll talk about the company, and I'll also spend a little bit of time in a few minutes talking about the succession changes we're going through. So stay tuned for that, but we always start with our credo. It kind of defines who we are, kind of the soul of the company, if we will. It highlights the fact that what we do is serious. And when we do it well, we're a trusted partner. And it's a team sport. We can't change healthcare by ourselves, but we can be an important part of it, and we need to be one that others can count on along the way. We work with a lot of constituencies. We were born in this multi stakeholder model, and sort of feel like we live that every day, so that's really not new to us. And we're also reminded by the clothes, why we're here. And it's to serve patients. And we know when we serve patients that the rest of it kind of takes care of itself. We take this seriously. We ask our employees to live this every day, and I'm so proud of our leadership team that they take it so seriously.

Our company continues to evolve. I don't know that you measure the company by what the sales are, or the profits are, but there's lots of ways of measuring it. Just transcatheter procedures themselves, over 800,000 so far. So we're not far from closing in on a million procedures there. Very proud to say almost everything we sell, over 95%, are in number one global positions. We have a really strong global supply chain that has not let down the patients that we serve. And so we're very global in nature, and that team has been so dedicated, and we have plans to make it even more robust. And we invest on that on a very strategic basis, routinely. A lot of smart people in the company, just over 2,000 engineers alone. And you know the kind of investment that we make in research and development, because innovation is one of our pillars.

And we also have a company where our employees are really engaged in charitable efforts. We have this aspiration that everybody will do something and over 85% of our employees reported doing something charitable in the last year. So we're up to 17,000 employees at this point. And although we have a lot of real deep experience with the company, we have a lot of new people as well. 60% of our employees are millennials and Gen Z. So we've got this cool combination of the deep experience, etcetera, but also the bright new minds, the bright new ideas, and I love the dynamic that's associated with that.

So our aspirations talk about who we want to be when we grow up, and we're constantly striving to do that. It really starts with this idea that we want to transform lives with breakthrough medical technologies. That's easy to say, but boy, when we get that, right, we just create incredible value. It's super hard and it takes a long time, but we're good with that. Right? That's who we are. That's what we try to do. When you think about what Edwards does for a living, serious things like heart valves, like critical care medicine, there's not a lot of room for mistakes. And so for us to be a truly trusted partner where people can count on our quality, count and our integrity, count on the fact that we're always going to try and tell the truth and be their partner is something that's so important.

We have a group of employees that we try and create an environment where they really feel like they belong, and they can grow to be their best. And we try and invest in that in a real way to have this inclusive culture where people really enjoy their work and value their work. We also know that we operate in a lot of different communities, and we want to be known as a company that gives back to its communities. Not a taker, but somewhere where you'd say, but we're glad Edwards is in our community, they make us stronger. And we really approach it with that kind of an attitude.

And finally, when we get all those other things right, I don't think we could help but create shareholder value. And that's the way we approach it, is from the top to create value through the way that we behave. So our strategy is different than other companies' strategy. Often, companies try and grow by diversification and so forth. That's really not who we are. At our core, we're committed to just continue to innovate. As great as healthcare is today and particularly for the patients that we serve, we feel like it could be so much better. And so we are committed to innovation, just constantly driving the state of the art to a better place.

Now, we know that the practice of medicine doesn't change very easily or very quickly, and you better back it up with big time evidence. And so that means the things that we embark on are going to take time, right? And we know that when we go start a journey, we might be at it for a decade or more before it really realizes its potential. And we're good with that, right? So it speaks to that innovation process. And certainly, there's risk associated with it because as good as we are, everything we start doesn't necessarily work out the way we thought. Sometimes the things we start work out even better than how we thought. So it's innovation at its essence.

We also are believers in leadership. We don't mind going first. Actually, it's lower risk to go second or third, but that's not the way we look at it. We say those that go first, they learn faster than anybody else and they're also at the table with the other pioneers in actually shaping the innovation in terms of how that'll work. And that's the chair that we want to be in. And finally, the way that we manage the risk associated with leadership and the risk associated with innovation is by staying focused. And so that idea that we're just going to stay maniacally focused on structural heart disease and critical care medicine, and not crowded with other things that are the shiny new object, that is powerful.

We think there's greatly underserved populations right there, and that we don't need to go to other places to have a lot of growth and a very bright future. And that focus really, I think, distinguishes us, and allows us to really know this group of patients and be better than anybody else, and to continually find ways of giving them better answers than they've ever had before. So when we get that right, we create a lot of value. If you're sort of reflecting on, how's it worked out so far? Not so bad. Not so bad. We know that the patient demand is tremendous, so we're going to talk more about that.

These patients are underserved, and much of it is because historically, there were no good answers for these patients. But if we do our job right, and we create innovations, there's going to be answers in the future like they never had before. We constantly strive for this triple win. And this is just a simple idea of just think, if we can extend life, improve the quality of life, and save the system money, ding, ding, ding. Right? That's what success looks like, and that's what we continuously try to do, is to get those triple wins. And as I mentioned, these are long-term efforts, right? This isn't about--I know I kind of smile. People are always wondering, well, what's next quarter going to look like or next year? We're in it for the long run, and that's what it really takes.

The success that we're enjoying right now are often seeds that were planted five years ago, 10 years ago. And we know that the seeds that we're planting today are the ones that are going to bear fruit in the future. And that's just the way life works for us. So we're going to go deeper on all these subjects, and so I won't go deep on any of them. We had a challenging environment in 2022, but we did quite a bit of growing and quite a bit of investing in the future during 2022.

We expect '23 to be a strong year of growth, as well as accomplishing some really important milestones along the way. We think there's a very large addressable market, and we're happy to get deeper with you on that one. And I'm so proud of this team. We got just a highly strategic and experienced management team that enables all this to happen. And so we'll get deeper on all that.

So '22 is a year where we actually had quite a few accomplishments, and we'll go deeper on that. And I won't go through all of it, but our teams really delivered. Even during a challenging environment, they made sure that we continue to meet our commitments and advance some of these long term efforts that make a difference. And even though we fell short of what we wanted to from a sales perspective, we still had some pretty nice growth that we enjoyed during the year, but we never lost sight of why we're here and our strategic aims in the long run.

The guidance itself is unchanged for the rest of the year. So we'll talk about that more and Scott will go much deeper in his section. Bigger picture, you guys all know this that follow the company. We feel like COVID really triggered some downstream staffing challenges, right? So probably was born during the age of COVID, but it ended up having a big impact on our customers. They just have had a tough time having all the staff in place that they need to have

in place, and there's plenty written about this. And we have not taken that lightly. That's really important. We have prioritized a number of initiatives to go exactly at this point, and we'll be talking about those during the course of the conference. It's multifaceted.

The thing that I'm encouraged by those folks that are running hospital systems or governments in big health care systems, they're equally motivated to solve these problems. In a fee for service world, the way that they get paid is to do procedures, and they want to do procedures. And so getting this squared away is something they're very committed to. I get a chance to speak with a number of them, and they're highly committed. And we believe that they're going to make progress on it and we're going to try and be good partners and do our part in helping them be successful.

So '23 is going to be a year which we believe is going to have strong growth and a lot of investment again in our future. And we're going to go through this business by business, and you get a chance to hear from each one with a fair amount of detail about the big milestones that we expect to accomplish during the year, at the same time that it would see a year of growth. And when you think about it, '23 we don't know how that's going to shape up for the world. Are we going to have a recession or come just come close to it? And so far, we think that we're going to be able to have some pretty solid growth during the year, regardless of what that environment looks like.

So let me just speak to the long-term. We continue to believe that we have incredible opportunity, and that patients out there are dramatically underserved, and that our opportunity will essentially double from where we are right now, between now and 2028. And there's a \$20 billion dollar market opportunity for us to go after, and that's what really motivates us to make a difference for these patients. And we'll get a little deeper on all that. And actually, beyond '28, and we talk about very long timeframes, there's some big movers that won't even be in place. Things like treating moderate aortic stenosis patients aren't even in those numbers and that's a very large opportunity.

We think, actually replacing valves in the mitral and tricuspid position will still be small by 2028, and the bigger opportunities are going to be well beyond and that's a very large one in itself. We also believe that there's going to be the opportunity for Edwards to use our kind of expertise to use interventional therapies to treat heart failure, the number one expense item, the number one killer in the world. And so we're excited about things on a long-term basis, and continually think about that as we make our investments.

Our--excuse me. Our agenda, you may have seen. You're going to hear from a number of our leaders. You know we've got some management changes going on, where people are going to change roles. Our leaders are going to present their current roles, not their future roles. And so you're going to see everybody doing the jobs that they have been doing and doing so well. So just a little bit of a preview for that. The people that are going to take new roles on actually take those on at January 1st.

And speaking of that, this is probably a good place for me to just talk about our team. I'm very proud of our executive leadership team. These people, each individually, are very experienced, very committed, and experts at what they do. But more than that, they're a real team. We really do help each other. We really do work together as a team, and it allows us to be successful. You know that I announced that I'm going to be making a transition moving from the role that I'm in today as CEO and Chairman, that next May, that I'll transition to, hopefully the Chairman's role. I'll stand for election for that. And that Bernard Zovighian will be the new CEO of Edwards Lifesciences starting in May. He'll be in the President's role, and he and I will work together very closely over the next six months to ensure a smooth transition.

This is not something that's come very quickly or without a lot of thought. Our Board takes very seriously the succession process. We've talked about it a lot. We routinely go through and have a number of successors for all the top jobs, including the one that I was in, and had a very rigorous process which included people both inside and outside the company and I'm really pleased to announce Bernard, and I think the company is going to be in very good hands with him. And those of you that don't know him, I look forward to you getting a chance to know him even better, because he's got an incredible track record of success. He's been leading our TMTT business, which is all the right stuff and creating something that's very exciting, and taking a dream and turning it into reality, which is really best of Edwards.

We also have new responsibilities for Larry Wood. You guys know Larry. Larry has been this incredible leader that has helped create the transcatheter aortic valve replacement business from scratch. And I'm talking about from zero, dedicated 20 years of his career to create probably one of the greatest innovations in cardiovascular medicine, if not more broadly than any of us has seen. We're so proud of his leadership. He's going to take on expanded responsibility, also have responsibility for our surgical structural heart business, and some other responsibilities inside the company. And so we're very pleased to be able to expand his responsibility.

And then when Bernard moves into his new role, Daveen Chopra, who's been running our surgical structural heart business is going to move into the TMTT job, running transcatheter tricuspid and mitral therapies. Daveen has a great track record, very passionate guy, very smart guy, and is very well prepared for this responsibility moving ahead. So I'm proud of this team, and one of the things that gives me a lot of comfort to sort of go on to the next stage is to know that we have this incredible team that really leads the company. And we are a tight team. And anybody that sort of things that it's all around one person has never seen the way that Edwards really works. So you'll get a chance to hear more about this as time goes on. And so with that, I'd like to introduce Larry Wood to talk about transcatheter heart valve replacements. And matter of fact, let's roll the video.

(VIDEO BEGINS)

Unknown Speaker

It is our responsibility to make sure that we are not under diagnosing and under treating aortic stenosis, because we have an excellent solution for these patients, and it makes a real impact in their survival and their quality of life.

Unknown Speaker

I'm 82 years old. I'm into hiking and guiding and stair climbing. I didn't want open heart surgery because I'd rather get back on the trail a lot quicker. TAVR made all the difference for me.

(VIDEO ENDS)

Larry Wood

Well, thanks, Mike. It's always great to see everybody, and it's always such an honor and privilege to talk about our transcatheter valve business. So I know there's been a lot of challenges of late, but we see those really is transient. The fundamentals of our transcatheter valve business remain incredibly strong. I think there's three pillars to our strategy that we really focus on: increasing therapy adoption, expanding indications, and delivering a strong portfolio that's highly differentiated.

Now, if we look back at the last six years, we know the last couple of quarters have been a bit tough but if you look at the dotted line, we can see that the growth of TAVR has been really, really impressive, and that line represents about a 14% CAGR. But we've never just been linear and stayed on that line. I remember back in 2016, many of you wrote notes talking about the demise of TAVR. And many of you wrote those same notes in 2018. But we always saw the return and we always saw the acceleration again, because the fundamentals are very strong and there's a huge patient population, as Mike said, that's underserved.

One of the questions that we've gotten a lot is, why does TAVR seem to be disproportionately affected by staffing issues compared to other procedures? Well, one of the things that happens if a patient with aortic stenosis or any valve disease is referred to surgery, they can be immediately scheduled for surgery because most of the assessments are done actually interprocedurally, things like valve sizing, the surgeon does during the procedure. But for TAVR patients, there's additional steps that they have to go through. They often get a confirmatory echo. They need a CT scan so that we can assess their sizing and access. They often have to be screened for coronary disease, and at the end, they have to be seen by a surgeon generic cardiologist and they go through a shared decision making process. So there's just more steps that require more resources to process a TAVR patient through the pre procedure aspects of it.

We've done a tremendous amount to try to optimize the procedure. We've reduced length of stay. Many hospitals in the country narrowed down to one day length of stay. The procedure time has come down from more than three hours to about an hour in most institutions. And there's a lot of things that we can share on best practices to reduce the number of people in the room and reduce that administrative burden. And there's a lot of hospitals that are

optimized, but there's many, many, many more hospitals that still are in that early phase of optimizing their staffing and optimizing their procedure.

Now, one of the things that we do to try to help the staffing challenges is we provide a lot of training and a lot of education. In an average year, we would train or educate about 200 valve clinic coordinators. Now, valve clinic coordinators are sort of the point person for the structural heart program. They're sort of the guide that moves the patient through the process and make sure they have all of their tests scheduled and tests performed, and that they see all the appropriate doctors along the journey. In a typical year, we run programs and touch about 200 valve clinic coordinators. This year, we're going to do well over 800. We might actually get close to 900, which just reflects--I only have 850 hospitals or so in the country, so it tells you how much staffing churn there has been and it's critical that we get the valve clinic coordinators up to speed.

So these educational programs are largely peer-to-peer, where we match up experienced valve clinic coordinators with new people to show them what it takes to be a valve clinic coordinator. And then we run advanced programs for centers that want to optimize their care and want to take on things like benchmark and other things. We also continue to train fellows, and we train additional heart teams, because as hospitals reach their capacity limit, they oftentimes have to get a second TAVR team up and running, and so we provide all the training for that. And you can see the numbers here, but we do a lot of training to try to address some of these staffing challenges.

Now last year, we talked a lot about our portfolio. And these are things that really impact us near-term and long-term. We talked about getting Alterra approved for pulmonic patients, and I'm very happy to report that did happen on time, on schedule. There was a product that we didn't talk about a year ago, which is our SAPIEN 3 Ultra with the resilia tissue technology. And we're very excited that's approved now in the U.S., as well as Japan. We have our SAPIEN 4--excuse me, SAPIEN X4 system, which is now in a clinical trial. We have our early TAVR trial, which we completed the enrollment, and all those people are on their journey to the endpoint. And we have the progress trial, which is actively enrolling for moderate aortic stenosis patients. So tremendous progress on both near-term and long-term activities.

Now, increasing therapy adoption is one of our prime strategies that we focus on a lot. And part of it goes back to looking at the disease itself. Aortic stenosis is a disease of the elderly. The older you get, the higher the prevalence goes, and it really is just sort of like a hockey stick. You guys have probably seen this curve in financial projections before, but this is actually aortic stenosis. And the older you get, the higher the probability is that you will have it.

When we look at the population itself, the largest growing segment of the population is the elderly segment, it's the over 65. 10,000 people a day turn 65. And by 2030, every single baby boomer will be over the age of 65. So this growing population is a huge part of the story. But the other thing is, when we started the TAVR journey and we used to talk to surgeons, the

people that actually provided the care, they told us that there was no under treatment, that everybody that was referred to them got therapy. There was really very few inoperable patients, if any, and there was no under treatment of the disease. But as we've gone really deep on this, we've learned that back pre-TAVR, only about six out of 100 patients with severe aortic stenosis got treated. And as evidence of the under treatment, you can see during this period of time, the number of people getting the aortic valve replaced is virtually doubled, which speaks to the under treatment.

But even with that, we've only moved to about 12 out of 100 people. And even when you look forward and you look at a lot of our projections, that number goes to like 16 to 18. We never get up into those really high treatment ranges that patients probably deserve. Under treatment is also a much bigger problem in the elderly. We see as patients get older, the utilization of valve replacement goes down as a percentage significantly. We also see that the time to treatment from diagnosis to treatment goes up significantly as people get older, and this really speaks to an issue around ageism.

Now, rather than just hear about this from me, we've got a couple of our key clinicians here and they're going to talk about their own experience with this and their own practice with this. So please cue the video.

(VIDEO BEGINS)

Unknown Speaker

TAVR has been transformative in giving us an option to treat patients who previously did not have a treatment option. We're becoming much more aware of the fact that there's a large segment of patients who have a guideline indication for valve replacement, severe symptomatic aortic stenosis, who are not getting treatment without replacement.

Unknown Speaker

When I first heard and saw data in the literature that aortic valve replacement was being underutilized, honestly, I didn't believe it. I went and looked at our own data, and we ended up finding that despite the fact that TAVR had been introduced, aortic valve replacement remained severely undertreated. Our own data has actually demonstrated that half of patients with symptomatic severe aortic stenosis do not get treated, and that's across the board.

Unknown Speaker

Imagine you had a cancer with a high mortality rate, you had an effective therapy, but only 50% of patients were treated with it, there would be a public outcry.

Unknown Speaker

Age is one of the biggest contributors to AVR underutilization. In patients who are over the age of 80, only 25% or so receive an aortic valve replacement, which is absolutely a dismal number, given the fact that we know that if you don't treat symptomatic severe aortic stenosis, only

about 50% of patients will survive one to two years. So it really is a medically urgent condition that warrants urgent treatment. On average, it can take over six months for a patient with aortic stenosis who's over the age of 80, to actually get an aortic valve replacement.

Unknown Speaker

The AHA created the target AS initiative to focus on patients before the time of treatment. To date, the entire focus of the quality of care of patients with aortic stenosis has been on the time from treatment with aortic valve replacement and afterward. We are attempting now through this initiative to look upstream to what happens from the time period of diagnosis by echocardiogram, through referral, to timely treatment of aortic valve replacement.

Unknown Speaker

So I think we will definitely be able to address these shortcomings and that the community as a whole will rally behind treating patients more fully.

Unknown Speake

The goal is to ensure that all patients with severe symptomatic aortic stenosis who warrant and desire aortic valve replacement, are treated in a timely manner with complications minimized.

Unknown Speaker

Once we do that, I think we will definitely have the ability to improve our patients lives, to make them live longer, and to treat more of them, and to keep them healthy.

(VIDEO ENDS)

Larry Wood

I think one of the most sobering things from that video is in elite cardiac program, such as Mass General, half of the patients who have a guideline indication for valve replacement, go without therapy. And if that's the situation at Mass General, I can almost assure you it's worse probably at most other places. So it just really speaks to the under treatment. So you want to dig into the why. Why are people reluctant to treat 80 year olds?

Well, the first question may be, hey, maybe because they're advanced age. Maybe we can't deliver good outcomes and 80 year olds with things like TAVR. Well, we look at the data, and basically the outcomes we can deliver in 80 year olds are indistinguishable from 70 year olds. So we know we can deliver spectacular outcomes from all of the clinical measurements that we have. So maybe you say, yeah, that's fine, but maybe these patients aren't going to get the quality of life benefits because they have so many comorbidities. So we went and dug into it.

And you look at very sophisticated quality of life measures like KCCQ, and again, the results are indistinguishable. You look at NYHA score, they're virtually the same. So clearly, these patients get the same quality of life benefits and survival benefits. So maybe you say, okay, but if a patient is 80, their life expectancy is so short, so why should we bother putting them through

this procedure and utilizing this technology? Well, the reality is, is if you reach the age of 80, chances are you're going to live another nine years.

So not only do they need an intervention, they need a high quality intervention. They need a durable intervention. So we know that we can do these things, but part of it is just our perception and bias of what an 80 year old is today. And this is Harrison Ford. He's 80 and he just recently filmed a new Indiana Jones movie. If Indiana Jones got aortic stenosis, he deserves a TAVR. And I think that's just something that we have to think about, and we have to change the way we approach what it means to be 80 now, in terms of life expectancy and in terms of ability to improve not only their survival, but also their quality of life.

So what are we doing about it? Well, we have a number of workstreams actively moving on this. We have television commercials that we run in the United States, as well as outside the United States, to try to raise awareness. And not just awareness with patients, but also their caregivers, and in some cases, their physicians. We have resources online to help patients find a TAVR center or educate them about the therapies that are available to them. And we partnered with Healthgrades to make sure that they can actually contact a doctor on the heart team, rather than have to go through a more complicated referral pathway.

We've also--the issue of agism is probably one of our newer findings. We sort of in our journey, we started with inoperable and high risk patients, and a lot of our focus has been on the lower risk in younger patients. But when we dig into the data, one of the things we discovered is it's still really the older patients that are most often denied care or move slowly through the system. So we've really tried to partner with key clinicians to attack this issue of ageism. And even at the most recent TCT meeting, there were symposia on this, there were key thought leaders who were speaking about it, and really trying to educate people on the data and the projections and the life expectancy of elderly populations to try to change this curve.

The other thing is, the AHA has started a quality initiative to really try to address the issues with the treatment for patients with aortic stenosis. This is a program that we support. But what it's really focused on is what happens to a patient before treatment, their time to therapy. We feel that--or AHA feels actually, that most patients from time of diagnosis to treatment should be 90 days or less, but that actually rarely happens today in clinical practice. So they're working with key centers. They're working to understand the data. But the goal of this is really to create guidelines and quality metrics from the time of diagnosis rather than just focusing on the clinical outcomes of the patient receiving treatment.

And the AHA is the perfect entity to lead this charge because they have demonstrated expertise. They led the door to balloon initiative, which pretty much revolutionized how patients with heart attacks were treated, and they've also done incredible work to address stroke to try to improve care. And a lot of it is based on timely identification and timely treatment, so we're very excited about this initiative.

There's no silver bullet here. There's no one thing, but we have so many different work streams targeted in so many different areas to try to address hospital systems, to try to reach patients directly, and to try to focus on the HCPs. And it's going to take a combination of all these things, but we continue to invest heavily in this, and we're excited with the progress we're making.

So expanding indications is also another key pillar of our strategy. We've talked about the under treatment of patients with severe aortic stenosis. And part of the challenge there is right now, the guidelines often relate to symptoms as being the trigger point for patients being treated. But because this is a disease of the elderly and the symptoms are often shortness of breath, or lightheadedness, or exercise tolerance, oftentimes, those just get confused with the aging process, and not attributed to the valvular disease.

Now, we don't think there's a lot of logic in waiting for the patient to actually have symptoms, rather than just treating the disease when it presents. We don't really treat other diseases that way. And so if we could get people and prove that treating them when they're diagnosed with the disease is the trip point rather than symptoms, it would really revolutionize how patients move through the system with aortic stenosis. So we have the early TAVR trial, which is completely enrolled. It has a two year endpoint, and we're just waiting for those patients to meet their endpoint so we can open up this data. But it's going to tell us for the first time ever, definitively what percentage of patients are truly asymptomatic when subjected to a protocolized stress test and how fast do they progress, and is there dangers in waiting to treat these patients?

And we'll be able to answer these questions through a high quality, randomized trial. And that evidence can help us define how these patients should be treated. Beyond severe aortic stenosis in this issue of symptoms, we have moderate disease. Again, most diseases, you try to treat them as soon as possible when they're initially identified. But with aortic stenosis, patients with moderate aortic stenosis are just told to wait, and they're told to wait until it gets severe. And several studies have shown that irreversible damage is being done to the heart during this period of time. So we believe treating these patients earlier could have significant benefits for these patients.

So we have the progress trial. Again, another very rigorous randomized trial, large sample size, where patients are going to either be randomized to getting therapy, or clinical surveillance. And the primary endpoint very similar to early TAVR. Again, it has a two year endpoint, and it has 10 year long term follow up. But this is the sort of evidence that we're going to have to generate if we want to change the patient journey and change how patients move through the system with aortic stenosis.

One of the reasons we're confident that this trial is going to show to be successful are recent studies that have come out that have shown that patients with moderate disease have almost the same trajectory as patients with severe disease. So maybe the trip point for treatment should be moderate rather than waiting until it's severe. But if this trial is successful, it basically

doubles the size of the TAVR opportunity, because for every severe patient, there's two moderate patients.

So the last thing is delivering on a really strong portfolio. We've enjoyed a highly differentiated portfolio during this entire TAVR journey. And you can see, we've had a number of meaningful innovations over time. Our latest innovation is SAPIEN 3 Ultra with the resilia tissue technology. We have SAPIEN X4 in the ALLIANCE trial. And then we have future platforms beyond that. We're just never going to stop innovating, and we're incredibly focused on making sure we always stay ahead, and we continue to deliver critical innovations for patients.

Now, Ultra resilia, this is the first time that any transcatheter heart valve has had dry tissue. The resilia tissue technology is on our leading surgical heart valves. I don't want to steal his thunder. My good friend Daveen is going to talk a lot more about resilia during his presentation. But having this on our platform, we think is a real game changer for physicians. And we also added the ultra skirt to the 29 millimeter. So now we have a full complement of sizes with our Ultra platform. So we're very excited about this. We're excited enough that for the first time in our history, we're actually raising the list price about \$1,500. And so we feel very strongly that this is going to be developments and innovations that are going to be valued by our customers, and we're excited about the opportunity.

The other platform that we have that's in our clinical trial is our X4. This is really a revolutionary platform. One of the major changes to it, is we introduced variable sizing. So right now, our valves come in three millimeter increments, but patients don't. And so we always have to adapt the patient to our valve size. But with SAPIEN X4, we've designed a valve that can operate over a wider size range. So if a patient comes in and their annulus is 24 and a half, we can take a 26 millimeter valve and deploy it to 24 and a half so we can have a valve that's very personal for that patient.

The other thing that we're able to do is we're able to align the commissures. So we can align the commissures on the prosthetic valve to the commissures in the native anatomy. And why that's important is for future valve and bowel procedures. The demands on a transcatheter heart valve now are much bigger than they were when we started. When we started, it was just about treating aortic stenosis, but now the valve has to be a great valve for fixing aortic stenosis, but it also has to be a great host for that next intervention. But then it also has to be a great guest that can go in that host because we're now thinking about lifetime management. How does the patient get two or perhaps even three procedures staged over the course of their lifetime? And that's what we think about when we develop these new platforms, is preparing not only for this procedure, but for future procedures.

Now, we did pause the enrollment in our ALLIANCE trial, because it's completely unrelated to the valve, but we found an opportunity with the delivery system, where we think we can really enhance the user experience. So we paused it because the bar that we have with our SAPIEN 3 Ultra platform is super high. We need to make sure that if we're going to bring a platform into

display SAPIEN 3 Ultra, that it hits all the marks and it's a 10 on a 10 scale. And we just see that there's an opportunity here to really improve and change the physician experience with the platform.

So we expect to go back into clinical trial next year, but it's really critical that we get this platform right. And so we're really excited about it. Again, it's unrelated to the valve. It's unrelated to the delivery of the valve. It just has to do with how we introduce the valve into the body. So we're excited to get that trial back underway. So again, we have our transient challenges with staffing and some of the hangover from COVID. But our fundamentals are so strong with the aging population and with the under treatment of this disease and we just think there's so many opportunities to reinvigorate the growth and go back to where we were pre-COVID.

When we look at the opportunity, we, again, still see this as being a \$10 billion opportunity by 2028, which is very exciting, but I think even more exciting is beyond 2028. It's not like 2028 is the end of the journey. We have things like (INAUDIBLE) aortic stenosis, the progress trial. Those probably don't really contribute before 2028. Those probably come later. We also have further global expansion into emerging markets, and those things are going to continue to contribute over time, but a lot of those things are going to happen after the 2028 time period. So we see this as having really, really a long runway to continue to grow very, very robustly.

So as we look towards 2023, we have the headwinds with the hospital staffing in COVID uncertainties, but we also have the tail winds of trying to drive this therapy adoption. And we do hear anecdotally that there may be a little bit of a patient backlog that's been growing, why some of these staffing problems have occurred. And so if that's the case, then that's also going to be a patient group that could help us in 2023.

So we've factored all of that into our guidance. And our guidance is 9% to 12% growth in 2023 and we're excited to be back in that arena. So with that, I'd like to turn it over to my good friend, Bernard. He's always been my good friend, but now he's my really good friend. And he's going to talk about our team TMTT opportunity. So thank you very much.

(VIDEO BEGINS)

Unknown Speaker

Having those innovative minds that Edwards have in managing a very complex disease that many people shy away from, is really what makes Edwards seize the moment in managing mitral valve disease. They pay attention for every single details in their clinical trial, and that gives you trust in the technology. That gives you a trust in the data and that actually gives you trust in a partnership for treating patients.

Unknown Speaker

After the procedure, I don't have to worry about shortness of breath, because I've got it all back and more. My quality of life is probably 120% better than it ever was.

(VIDEO ENDS)

Bernard Zovighian

Thanks, Larry. Hello, everyone. I'm very pleased to be here with you today. Over the next 20 minutes or so, I'm going to share progress, meaningful progress we made, the exciting plan we have toward achieving our vision of transforming care for so many patients in need. So I will start with the patient need, get into the mitral then tricuspid and then I'll wrap up. So let me start with the patient, the patient need.

Let me tell you that what these patients are experiencing is very tough. The mortality for this patient, both mitral and (INAUDIBLE) is very high. They have a very tough quality of life. And the physician have very few options. I can't see the slide here. Sorry. They have very few options (INAUDIBLE) drugs. So most of these patient are (INAUDIBLE) medically and we know that it is somehow effective, very costly. Patient have a lot of rehospitalization. So tough on the patient, tough on the healthcare system.

When they get an intervention, it is mostly surgery, so very invasive. The recovery is long for the patients. So if you think about what we believe, we believe that transcatheter innovation can change this, can change the adoption. So today, the adoption for both surgery and transcatheter is about 2%, very low. We believe that transcatheter innovation via the adoption can go to 4%. So 4% in my mind is bringing you two things. One, it is realistic, correct, 2% to 4%. It is still a low number of adoption, and we believe therefore, that there is great growth beyond 2028.

How we are going to do that, with a proven strategy, what we have been doing in TAVR for a long time, having best innovation, great clinical evidence, being able to support physician partnering with physician to achieve a great outcome. We believe that the adoption going from 2% to 4% of a transcatheter segment will basically grow from what it is, one billion today to five billion by 2028. So great opportunity ahead of us in transforming care for this many patients.

Here, I have a technical challenge. I don't see the slide. So let me start with mitral sections. In the past, physician have only one innovation, one (INAUDIBLE) device. The clinical evidence were limited and mixed, and many patient were discharged from the hospital with only being able to achieve moderate (INAUDIBLE), which we know today is not sufficient. I am confident that the new era is starting. If you look at what we have today, there are two devices available. The innovation is way stronger. Many innovation has happened in the last few years.

Clinical evidence also have made great advances. The device are easier to use. More operator can learn how to use these devices. Tomorrow, we see this trend continuing with more innovation (INAUDIBLE) and the addition of mitral replacement, more clinical evidence. So we

are for sure--we are very excited about today, what's happening, but also very excited about what lies ahead for patient and physician.

Let me start with year-over-year innovation, because at the end of the day, it is all about having great innovation. And we introduced you to PASCAL Precision in Europe earlier in the year, in the U.S. earlier in the year, and we are hearing your great feedback from physician. What we see (INAUDIBLE) word of caution, but we like what we see, (INAUDIBLE), enhanced patient outcome. So we are very committed here to bring a number of innovation in the years to come. We are very pleased about PASCAL Precision today.

Let's listen now to what physician are seeing about PASCAL Precision.

(VIDEO BEGINS)

Peter Hughes

Hi, my name is Peter Hughes. I'm 78 years old. My wife and I live a quiet life in the countryside. It gives us excellent relaxation. 18 months ago, I noticed that my energy level was diminishing. I also had some difficulty breathing, and my sleep pattern deteriorated.

Unknown Speaker

Peter had really quite debilitating symptoms and his mitral regurgitation was becoming more severe.

Peter Hughes

Open heart surgery was definitely not an option.

Unknown Speaker

The PASCAL device gives me the opportunity to treat the full range of mitral valve anatomy safely with a very reliable result. Peter's procedure went very smoothly.

Peter Hughes

I was in in the morning, out in the evening. And in two days' time, I was feeling the benefit of having the mitral valve procedure. It has allowed me to be far more active, mowing the lawn, going to the bowling club and walking with friends.

Unknown Speaker

To be able to offer a patient like Peter a procedure like this with no further surgery with a very short inpatient stay is a fantastic advance in the treatment of severe mitral regurgitation. And with PASCAL Precision, there's been a big step forward in the ease of use of the device, which I'm sure will lead to more adoption in more centers.

Peter Hughes

It has made a significant difference to my quality of life.

(VIDEO ENDS)

Bernard Zovighian

So it is great to see this kind of impact we are making on patients and what PASCAL Precision is bringing to physician. So now, let's look at the clinical evidence on (INAUDIBLE), again, in a more deep you know manner here. So in the past, in the last few years at discharge, half of the patient were left with mild MR, which we know today is not sufficient. What we have seen lately, is that the latest evidence like the Class 2D randomized study. But overall, also, is that today when your reality is that your physician can achieve 80 plus percent of a patient being discharged with mild MR, and we know that this is having a big impact on patient mortality, patient's quality of life. So we are very excited about that. We see that being the new era for (INAUDIBLE), for (INAUDIBLE) mitral patient.

What we have seen also, and you have seen that at TCT, even though it is very early, even though it was the first cohort of patient that were presented at TCT, that PASCAL at six months seems very durable. And so we feel very good about that. Obviously, we are going to follow this patient out to five years. We want to bring world-class evidence. And next year, what you are going to see is the full cohort of patient from Class 2D at one year. So important data set that we are going to share with the medical community next year.

Now, let's look at--listen from the Class 2D PI and what we believe Class 2D is going to do to patient, to physicians, and to (INAUDIBLE) community.

(VIDEO BEGINS)

Unknown Speaker

The first randomized trial in (INAUDIBLE) therapy happened more than a decade ago.

Unknown Speaker

We now have even more data about the feasibility, the safety and efficacy of edge-to-edge repair technology for degenerative MR patients.

Unknown Speaker

Class 2D was conducted in a way that sets standards, and when a trial is rigorous, it is much more likely to have an impact on the way we practice cardiology.

Unknown Speaker

In both arms, nearly 98% had two plus or less MR. And in the PASCAL arm, nearly 84% had one plus or zero residual MR. There are several unique design features of the PASCAL device, its hollow nitinol construction, its smooth rounded surfaces, its ability to flex with the heart, that all along have given us a lot of encouragement that this device may be really offering something

quite important to our patients with mitral valve disease. And I think that's borne out by these trial results.

Unknown Speaker

The Class 2D data and the results thus far are huge.

Unknown Speaker

Now we can point to something and say, you know what, within six months, we've got some pretty remarkable results.

Unknown Speaker

I think this directly will translate into the confidence level of our referring physicians.

Unknown Speaker

So I think it will increase the patient flow that come into multidisciplinary teams to evaluate patients for tier therapy.

Unknown Speaker

Class 2D is a big deal for patients, so I think it's going to be very impactful.

(VIDEO ENDS)

Bernard Zovighian

So we are confident that we have a right platform today. It is a leading platform. Confident that Class 2D is bringing meaningful evidence for physician to treat (INAUDIBLE) patient. And so now let's go into what are we going to do in the U.S.? And we got slightly early approval in the U.S. We were very pleased with that. We launch at TCT. We started building a team, dedicated TMTT team about a year ago. We hire people, train people, scale this organization for them to deploy our high touch model.

So what we mean when we say high touch model, we mean we want them to train physician. Even though PASCAL is a tier device, it is a very different device than the current--than the former device in the marketplace. We want a high touch team to help support physician, screen patient. We want them to be in every case to make sure that every patient is well taken care of. So throughout 2023, what you can expect is us expanding our presence in large experience in the U.S., further hiring and scaling a high touch team and delivering exceptional results for every patient.

We are implementing a price premium strategy like we are doing in Europe. It is a modest price premium, nevertheless a price premium, which is in our mind aligned with this platform and what we bring to the value, we bring to (INAUDIBLE) system, to patient and physicians. So we are very excited about where we are with tier. It is important. It is an important segment. We have the right technology. Evidence is coming in strong.

At the same time, we know that this patient population is very complex, very diverse and we need to complement tier with the mitral replacement therapy. Replacement can eliminate MR in a consistent manner and physician will be able to treat even more patients. We also know that not all transcatheter replacement are the same, and we learn that you know from TAVR. Transfemoral is less invasive than transapical. Transepithelial is a surgical platform. So with transfemoral, what do you get? Less bleeding, less complication, faster recovery.

What we also know is not all transfemoral are equal. The smaller they are, the better. You have less complication. So in a nutshell, we strongly believe that transcatheter, transfemoral, smaller French size, it is what will be key to success here, having effective therapy and very safe therapy. So the next question that everybody is asking us and me is, so, why are you currently developing two platforms? I think the answer is very simple. One, is we are committed to leadership. We know that if we want to unlock this large market potential and treat this underserved patient population, tier is not going to be sufficient. Replacement is necessary. So we are committed to bring a game changer here to complement (INAUDIBLE).

We also know that developing a mitral replacement is not easy. As a company, we have done that for 60 years. So having two platform give us the insurance of leadership. And the good news is we have two platform doing very well. (INAUDIBLE) is running. We are running a single arm study in the U.S., and then we have the SAPIEN 3, which is leveraging basically--the SAPIEN 3 most proven valve is--we are running pivotal studies with three arm. And basically, we expect completing enrollment of the main cohort around the end of next year.

So in a nutshell here, we are very excited about our progress. We are committed to significant mitral milestone in 2023, across three key valued rivals, bringing best Innovation, world-class evidence and being able to achieve in a real world great outcome for every patient. Super excited about what we are going to do for mitral patients.

Now, let me shift gears to tricuspid. In the past, it was the forgotten valve. It was highly under recognized, undertreated and therapy option were very limited. What we see today is in a clinical study, is a rapid trial adornment that I'm sure when you look at medical convention, there is an increase in clinical research. People are talking more and more about it, as early as TCT. We are dedicated (INAUDIBLE) tricuspid sessions. In Europe, we see a growing commercial adoption of our PASCAL for tricuspid patient. So clearly, transcatheter therapy have fueled interest.

What we see tomorrow is that with strong evidence like our Class 2 (INAUDIBLE), all of these have a potential to change the practice of medicine here. And for once, forgotten valve can emerge as the unforgettable valve. So it is truly exciting to see that. I see the promise. It is still early but I see the promise.

Now, as I think about this evolution, I am confident in our ability to lead and transform and address this large unmet patient need. Let me start with PASCAL first and then I will talk about EVOQUE. PASCAL Precision here is also very impactful in tricuspid patient. The tricuspid valve is very fragile. It has thinly flat dense (INAUDIBLE), large (INAUDIBLE) gaps. And what we see is we are very pleased what we see from PASCAL. Great in real world. (INAUDIBLE) from the few study we presented at (INAUDIBLE).

At (INAUDIBLE) as a matter of fact, we presented eight study across mitral and tricuspid. Three on tricuspid with PASCAL. All of that is (INAUDIBLE), positive. We need to be very cautious all the time, (INAUDIBLE) but very positive. So for instance, (INAUDIBLE) which is our study, real world, post market in Europe, almost 20 patient, we're able to (INAUDIBLE) a great outcome. High (INAUDIBLE) success, low complication rate and patient felt better, way better. So super exciting for these patients.

Now, let me jump into EVOQUE. We also presented at PCR London Valve, one year, TRISCEND single arm with EVOQUE. More than 100 patient and one year follow up is meaningful for valve. We know that as a valve company. But I want you to look at two metrics. The first one is mortality. When tricuspid is left untreated, the mortality rate is between 30% and 45% one year, big number. EVOQUE, one year with the study, again, preliminary, 10%. That's a big difference.

The second metric I want you to look at is the reduction in TR. One year after treatment, 98% of these patient are down to mild. They feel way better. So we are very excited about the potential of what this platform can do to this patient. Obviously, we need more data, and we are very committed to world-class evidence. We are running a pivotal study, a randomized study for symptomatic severe TR. It is randomized, basically EVOQUE against OMT, optimal medical therapy. And we expect--the enrollment is going very well. We expect enrollment to be completed by mid-next year.

So we have, as you can imagine, a lot of confidence in this platform. We leverage all of our know-how as a company, how to design a valve, the tissue technology, the delivery system, it is (INAUDIBLE) French, and we are committed to bring even more innovation. So in term of impact to patient, we are aiming to achieve a CE Mark approval by the end of next year, and a U.S. approval by the end of the year after, 2024.

Let me wrap up your tricuspid here. Here also, very committed about big, impactful, impactful milestone in 2023 across innovations, clinical evidence, achieving a real world outcome. Now, let's go into revenue for next year. So yes, like many med tech company, we see the potential headwinds, the regulatory environment in Europe, especially, for businesses like ourself, where we bring novel therapy to market. Also, obviously the staffing, COVID stuff happening in the U.S. and Europe. So we see that as a potential headwind. We also see potential tailwinds with all of the evidence we are bringing. Again, the beginning was a TCT pivotal study, Class 2D, eight presentation of (INAUDIBLE) valve, many more to come.

Can we accelerate adoption? Can we also accelerate the (INAUDIBLE) growth in the market? So we took all of that into consideration. And this is how we think about next year, having this range between 160 and 200 million. What I want to do is wrap up this TMTT story and you to remember basically two things. I am confident that the combination of best technology, a portfolio of technology to be able to treat this very complex and diverse patient population, world-class evidence and partnering with clinicians like we know how to do as a company, we have the potential to transform care for the many patients in need long-term.

I am also confident that 2023 will be another high impact year on this remarkable journey. Thank you. With that, I want to introduce you to Daveen Chopra, who is going to talk about our surgical businesses. We are going to do another transition, Daveen and I. Five years ago, we transitioned the surgical business when he joined our company, did an amazing job. And now he's going to take TMTT to next level. Thank you.

(VIDEO BEGINS)

Unknown Speaker

It's been a transformative decade in cardiac surgery.

Unknown Speaker

(INAUDIBLE) in the past.

Unknown Speaker

So that means that the (INAUDIBLE) volumes have increased, but it also means that our surgical volumes have increased.

Unknown Speaker

Aortic valve surgeries continue to be done at a rapid rate, as is mitral valve surgery, as well as other structural heart surgery.

Unknown Speaker

And they're coming sicker, more advanced in their disease, needing multiple valves or multiple procedures on the same patient.

Unknown Speaker

And therefore, the pressure on the surgeon to handle these more complex procedures is only going to increase.

Unknown Speaker

Having a partner like Edwards that listens to what we tell them is happening on the field to partner together is the only way we can help patients live their full potential.

(VIDEO ENDS)

Daveen Chopra

Thanks so much, Bernard. I appreciate the introduction. It's going to be fun to transition over to TMTT, and I appreciate all your leadership in the transition to come. But today, I'm excited to talk to you a little bit about the surgical structural heart business. And I think as you heard from both Bernard and Larry, structural heart disease therapies are growing. They're growing across the world. And as a result, we see that surgical structural heart market will continue to grow in the mid-single digits, where we believe that this market will exceed \$2 billion by 2028.

If you look at what's driving the overall surgical structural heart market, we see that these macro trends, as Larry talked about, there's obviously an ageing global population. There's also growing access and wealth in emerging markets. And we see that new structural heart innovations, especially transcatheter technologies, are helping increase overall awareness for structural heart disease. And we think that overall awareness is going to drive more diagnosis of patients, and eventually more referrals to heart teams. And when you get to heart teams, there's always going to be a group of patients that are best treated surgically. And that's what we see growing the surgical structural heart market.

If you look at the legacy of Edwards Lifesciences, for over 60 years now, we've been partnering with leading cardiac surgeons to understand patient unmet needs, to invent amazing new technologies and then bring them to market. And we've seen this innovation cycle lead to not only many amazing innovations, but if you look today at our business, over 50% of our revenue comes from products that were just launched in the last five years. And so we have a vision as a business to continue to work with these cardiac surgeon leaders and meet other unmet needs for patients and leading transformative innovations.

If you look at the unmet needs of surgical patients today, you see that patients today are still looking for extended durability, and lifetime management with their valves. They're looking for great solutions to complex and concomitant cases. And they're also looking for best in class innovations globally, not just in the U.S. And with that in mind, we, quite a few years ago now, invented what we believe is the leading resilia tissue that we believe will really provide the greatest durability.

If you look at tissue valves over time, the greatest way that they fail over time is through calcification. What resilia does is it effectively stops those calcification formation pathways, allowing a valve to have greater durability over time. And what you see with the resilia tissue is that patients are able to have an active life, to have a life where they don't have to have a mechanical valve and the anticoagulation and life (INAUDIBLE) tradeoffs that come with that. They're free to have the confidence to live the life that they want.

We've got and now built an amazing amount of clinical data around the resilia tissue. We see now that through two pre-market studies of over 800 patients, we've had zero structural valve

deterioration at five years of follow up. We're continuing to follow many, many more patients in the post market. We have over 14 different post market studies now, enrolling over 6,400 patients with resilia tissue that provide a great foundation on how resilia works in patients.

And as we look into 2023, we've actually got a couple important clinical milestones. The first one is that in mid 2023, we're going to present pivotal data, pivotal seven year data on the resilia tissue. So this is now with seven years of follow up. If you know with many kinds of tissue valves, when you get past the five year mark, you start to see kind of linear, significant deterioration. In our benchtop testing, we've really seen that resilia seems to last a lot longer than previous generations of tissues, and we believe now that this clinical data will help prove that out at seven years of follow up.

We'll also see that in early 2023 we'll start enrolling in our MOMENTA (PH) study. This is for our MITRUS mitral valve, and it will be a very large, multi-country, multicenter core lab adjudicated study to get a great set of data on our newest MITRUS mitral valve. If you look at what we've done with resilia tissue, we've now on the surgical business in addition to now the TAVR business, put it on three different surgical platforms. The first platform, our first product is our INSPIRIS, our flagship surgical aortic valve. And this obviously has the extended durability treatment, but also beyond resilia tissue, it also has this v-fit expandability.

What this means is that over time, if you need to go back in and reintervene on this surgical valve, you can actually enlarge the valve, make it bigger so that you can get a larger TAVR valve in there, which will lead to better clinical outcomes over time. What we've seen in 2023, what we believe in 2023, is that the continuous kind of INSPIRIS adoption is what's going to keep-- global adoption is going to grow the business in 2023.

Our second resilient platform is actually our KONECT aortic valve conduit. Now, this is a product for very complex patients, patients where you have to not only replace the valve, but the root as well as the ascending aorta. And what this product does, is that it really helps streamline procedures for physicians as well as for patients with a preassembled design, So it makes it so much easier. And if you look at this market, the market of these complex aortic valve replacements, we think in the U.S. it's actually growing high single digits. So the market for these complex procedures is growing high single digits, and we believe in 2023 that KONECT will easily outpace this market growth.

Now, switching gears over to mitral valve replacement, an area of a lot of opportunity for Edwards. We see that valves need to be replaced sometimes when you can't repair the valves because of tissue quality. It's a reoperation, rheumatic disease, endocarditis, etcetera. And we see that patients are looking for better options. Overall, this market globally is about 200,000 patients growing in the mid-single digits. And around the world on a global basis, the vast majority of these valves now are actually mechanical valves with the tradeoffs with anticoagulation and lifestyle.

However, in the U.S. specifically, actually, porcine valves are the most used valves in the U.S. And we see here that actually patients are looking for a more durable solution than porcine valves. And this is where our MITRIS mitral valve comes into play. Not only featuring resilia tissue, as I talked about previously, it includes other kinds of lifetime management features as well as ease of use kind of features. We actually believe that with this valve, which we launched in the U.S. in mid 2022, that in 2023, Edwards will then become the mitral valve replacement leader in the U.S.

I'm excited to share a little bit more about one of our patients who really benefited from the MITRIS product, Rick, and his physician, Michael Chu.

(VIDEO BEGINS)

Rick

I had rheumatic fever as a teenager, and a few years ago, got to the point where I'd have to stop and catch my breath.

Unknown Speaker

To go from climbing 60 feet silos to not being able to walk to the barn, it was very concerning.

Michael Chu

Rick was completely unwilling to consider a mechanical valve because farming was his livelihood. It was a part of his DNA. And he felt that being on a blood thinner permanently would have prevented him from doing his work. I talked to him about the opportunity that we have to be able to implant a new generation valve, the MITRIS resilia mitral valve, which takes advantage of the previous success of the (INAUDIBLE) design but adds in the promise for better durability with the resilia tissue. The MITRIS resilia prosthesis has a nice low profile. The radiopaque frame also facilitates future transcatheter intervention if it's needed, although we hope this valve will last for the rest of his life.

Rick

Once I was out of the hospital, the shortness of breath, it wasn't there anymore.

Unknown Speaker

Today, he's doing great. He just carries on life like he did before, so I don't feel the worry that I used to.

Rick

I feel much better, much better. Life is good.

(VIDEO ENDS)

Daveen Chopra

It was awesome to see Rick return to his life that he loved to lead with the MITRIS valve. Moving for a minute over to mitral regurgitation. I think as you saw Bernard say, of all the people with mitral regurgitation in the U.S., only 3% of patients who have mitral regurgitation actually get treated. And if you look specifically at the low risk degenerative MR patient, surgical mitral repair, surgical mitral repair is indicated for the low risk degenerative patient.

If you see it going forward in the future, we obviously see that many, many more mitral patients can be treated with the advent of transcatheter technology, but we continue to see that for the low risk degenerative MR patients, we believe surgery will continue to be indicated for this group of growing patients. However, when you look at this group of surgical mitral repair patients, getting a consistent high quality surgical repair is tough to do. We've seen recently from core lab adjudicated multicenter data that as high as 16% of patients at two years of follow up don't have an optimal surgical repair.

So we think this is an opportunity to improve upon this 16%, and that's where we're working on a product called the mitral adjustable repair system. This is a product that--a surgical product under development right now, that will enable beating heart adjustability of the implant. You can change the implant size during the procedure to really eliminate any regurgitation and hopefully, it will lead to more consistent great outcomes for surgeons and for patients.

So as you move forward to 2023, we see with the surgical business that our estimated revenue range is between \$870 and \$970 million, or approximately a mid-single digit growth rate under an underlying basis. Some of our headwinds are that there could be additional TAVR conversion that would happen in some other developed markets around the world, and there's obviously always going to be overall healthcare spending pressures. But we can see that perhaps that we can get additional tailwinds of increased resilia penetration that could come along for maybe more tissue to mechanical valve conversion on a global basis.

So in summary, we see that the surgical market is actually continuing to grow, especially those who have these complex concomitant procedures. We look at Edwards surgical continuing to outpace market growth coming from our resilia innovations out there. But beyond just resilia, there's a lot of other unmet needs. There's a lot of opportunity as for Edwards to continue to identify those unmet needs in these surgical patients and invent amazing innovations for them. Thanks so much.

I'm very excited now to introduce a good friend of mine, Katie Szyman, to come on and talk a little bit about the critical care business.

(VIDEO BEGINS)

Unknown Speaker

We are incredibly grateful that people have developed these tools for us and allows us to pick and choose what we think is relevant to us to help improve patient outcomes.

Unknown Speaker

Our real aim is to make all of this technology a part of our daily lives in hospitals all over the world.

(VIDEO ENDS)

Katie Szyman

Hey. Good afternoon, everyone, and thank you all for giving us a reason to come to New York during the holiday season. I'm personally super happy to get some shopping done after today. So it's just great to see everybody live here and have a chance to be together, so what a great day. So I'm here to give you an update about the critical care business and I wanted to just first of all share with you our strategy for growth.

So our goal is to grow critical care really through three major areas. The focus, first of all, on improving the quality of care for millions of patients throughout the world. We're super proud that this past year we hit a milestone of improving care for approximately 16 million patients, and we're really doing that in three key ways. One, is through bringing out new technology. The second is through bringing out clinical evidence, and the third is driving adoption.

So let me walk you through a little bit more about that. But before we get started, I first want to share with you an amazing patient video, sharing a little bit about a story of someone who's very close to our heart, one of our sales rep's mother. So let's play the video.

(VIDEO BEINGS)

Unknown Speaker

Last year, I have a very severe asthma attack. I keep trying to get air out of my chest, and it was just panic.

Unknown Speaker

It's hard to put into words what my mom means to me. She's my North Star. So I had to try with all my might to do something for her. So I got to the hospital, and she had been there for over 12 hours. So I kept asking the charge, what's going on with my mom? I determined after looking at her parameters that her blood pressure was dropping pretty rapidly. I called the nurse in, and I said, hey, my mom's hypotensive. She was like, you're right, there is a problem here, I need to go call the MD.

Unknown Speaker

I saw my little girl growed up. Now she's there helping save my life. I feel really great today, and I'm able to continue making memories, creating moments. That's the most precious gift to give someone.

(VIDEO ENDS)

Katie Szyman

So that's really the reason why we all get out of bed every day, to make a difference in patient lives. So first, let me talk a little bit about the hemodynamic monitoring market. So if you think about hemodynamic monitoring, there's really two kind of ways to think about it. First, is core monitoring, which still remains the majority of our business today. And in core monitoring, we're providing basic blood pressure information on a continuous basis of outpatients.

When it comes to smart recovery and smart monitoring, what we're doing is taking our basic blood pressure information, waveform, and coming up with additional parameters like cardiac output, stroke volume, and really giving advanced monitoring information to clinicians so they can better care for their patients. So today, the market is about \$1.2 billion where we have--you can see about a third of our disposable revenue comes from this smart monitoring category. And now we see in the future, it going to about \$1.8 billion, where we're continuing to see the higher growth aspect is smart monitoring, growing those smart sensors and smart technologies. And what that means is smart monitoring, plus faster recovery, getting patients home to their families faster, equals smart recovery, and that's what we're all about.

So let's talk about the three components of that. One is technology; second, evidence; third, is adoption. So smart recovery really begins with technology. And I love this pyramid because it kind of encapsulates everything that we do all in one slide. So at the foundation, we have our smart monitoring platform. HemoSphere builds that foundation. It's artificial intelligence enabled. It then has on top of it our algorithms, and every year, we come up with more smart algorithms that enable our smart recovery technology.

And then finally, we have our sensors. And we have what we would call our classic sensors of flow track and clear sight in the smart recovery category, and we're systematically going through and coming out with an IQ sensor, an IQ cuff in each of those categories. And you need to have one of the IQ sensors in order to unlock our hypotension prediction algorithm. These sensors create more value, and they are at a higher selling price overall.

So what we're doing, as we call it, we're smartifying (PH) our entire portfolio, taking our basic sensors, and shifting them to be smarter IQ sensors. So what is the difference in the algorithms? So first, our monitors always will describe to you how your patient is doing right now, this moment. With the hypotension prediction indicator, we're actually able to predict and tell clinicians what's going to happen for their patient 15 minutes from now.

And then finally, what's coming out this next year is our prescriptive algorithm, which is basically saying that fluid is like a drug to our patients. And we're able to make fluid recommendations or prescriptive recommendations to clinicians, again, in order to improve the patient outcomes. So the foundation of all of that is our HemoSphere platform. Similar to the iPhone, I kind of am making this argument that it's similar to the iPhone, but we actually came

out with the original HemoSphere in 2017, 2018 timeframe, and we are already on the seventh generation of that technology.

Each year, we've come out with a new HemoSphere that either adds a sensor or adds a new algorithm. So that you see now that we are in this process of rolling out the HemoSphere into our installed base, and in 2023, by the end of next year, we'll be just over 50% of the rollout of the HemoSphere technology. And by 2028, we would be fully rolled out with HemoSphere. And now, we're starting to shift and continue always to shift our focus to also expand. So not just replace the existing install base, but then to expand into new hospitals with our Smart Recovery technology. And you can see all of the sensors that are used with our HemoSphere. And you can also see the new thing that's coming out with HemoSphere this next generation, is our connectivity solution, where actually clinicians can see the patient's data. Whether they're in a different room, or whether they're supervising some of the nurses, they can actually see on the iPhone, how their patient is doing today.

So what does that mean? So as we shift towards smart recovery, today, about 15% of our sensors are the IQ version of the sensors. And as we look to the future, we see that becoming more than 50% of our sensors. And so that's really going to drive the growth in smart recovery is this conversion to using the more advanced sensors. On HemoSphere seven, as I mentioned, we have multi-tech monitoring, the ability to have two sensors on at one time for one patient, we have an advancement in the hypotension prediction. And then finally, we're launching assisted fluid management, that predictive area of our algorithms.

So I could talk all day long about how amazing I think smart recovery is, but I think you'd like to hear a little bit from one of our clinicians, Dr. Ashish Khanna. So let's roll that video.

(VIDEO BEGINS)

Ashish Khanna

HPI has really revolutionized what we do for our patients in the operating room. It allows me and providers like me to get ahead of hypotension. So rather than react and respond to blood pressure that we actually see as low on the monitor, we are now able to anticipate hypotension and prevent it from happening. More importantly, I feel HPI has allowed me to understand why hypotension is happening or is going to happen and allow me to find the most appropriate and precise treatment for hypotension.

(VIDEO ENDS)

Katie Szyman

So beyond just the smart technologies, one of the challenges that we have is, how do we convince clinicians that they should actually adopt and use our advanced algorithms? It's a bit like your iPhone. When they come out with the software change, you're like, really? This is frustrating. I don't want to have to deal with any changes. So as we've come out with

hypotension prediction, that represents a change to fundamentally how clinicians are used to treating low blood pressure events for their patients.

And so we first did an original study that I showed you last year, where we were able to show that we can reduce the average duration of the amount of time a patient is in a hypotensive state by 58%, from 28 minutes down to 12 minutes. You can see on the other side of the page, the number of studies, large studies that are trying to say, if you reduce the duration, can we also improve the outcomes, specifically AKI? Reducing acute kidney injury is a big impact if you can reduce hypotension during the procedures.

So let me show you one of the specific multicenter hospital quality projects that we did, and that we published this past year. So this is three centers here in the United States using hypotension prediction in their cardiac centers. They had 1,400 cardiac patients, and they were able to show versus their baseline that they were able to reduce the mean ICU length of stay by seven hours, and a 34% reduction in total ventilation time. And as I'm sure you know, that's very impactful to the patient's recovery and their ability to get back home to their families faster. So we're really proud. That was not presented at the AATS this past May to all of the cardiac surgeons that were attending.

So now, let's talk a little bit about awareness. So in the awareness area, what we're trying to do is just raise awareness of the importance of hypotension and that hypotension matters. So first of all, this past year, the OIG, the Office of the Inspector General, published a report that said that hypotension during surgery is one of the top five potential causes of harm to patients, which really raised awareness significantly.

The second is that we did a partnership with U.S. Anesthesia Partners and North Star Anesthesia, representing North of 50% of the total anesthesiologist here in the United States. And they just published last month at the ASA, they presented their findings that in over 150,000 of their patients, they found that roughly 28% of these patients had a mean arterial pressure below 65 for more than 15 minutes, which was really significant. And this was all range of patients high and low risk patients.

And then finally, as you probably know, CMS came out with a quality measure where they are actually reimbursing clinicians, anesthesiologist, if they can demonstrate that they're keeping their patients above that mean arterial pressure of 65. So really kind of making it important to them in terms of how they're actually reimbursed as well. So we're making progress, but of course, awareness and adoption are so important. Really, it's going to take some time. As Mike mentioned at the opening, clinicians, and in fact all of us, resist change and it's hard to kind of get adoption. So we've got to keep coming out with evidence and keep raising awareness on how important that is.

So as we look to the next year, we're very optimistic about this next year. We have estimated, again, mid-single digits in our growth rate. One of the biggest factors for us is how the recession

is going to impact capital budgets. We've seen kind of a big catch up in 2021. It stayed up there in 2022. And so as we look at next year, it's always uncertain how the recession will impact the hospital capital budgets. But on the flip side, the adoption of our IQ technologies is going quite well, and we really see this real world data continuing to drive adoption.

So in summary, I'd just like to say thank you for listening. It's just a great time here in the critical care business. We're leading the smart recovery with our artificial intelligence enabled technology. We are truly reaching more patients, to 16 million. We have a vision to hit 20 million by the year 2025. And we are gaining the adoption, most importantly, to be able to get patients home to their families faster. So I think in critical care, as we always say, We believe the best is yet to come.

So now, I'm happy to be able to turn all of you over to your first break of the day. Thanks, everybody.

Scott Ullem

All right. Look at that. The room quieted all on its own. Thank you. Well, there's no walk up music, or video for the finance presentation. We'll try to make it interesting anyway. So you've heard a lot this afternoon about the path that we're on for Edwards to become a leader in this new era of structural heart innovation. And we're especially excited about the opportunity Edwards has to make a difference by introducing new therapies to more patients around the world.

We're also enthusiastic about the prospect of creating impressive value for shareholders. And so it's timely and topical, that we're sitting here at the New York Stock Exchange at the end of the year, that's been tough in the stock market, and especially tough for Edwards' stock. But I'm really excited to be here and talk to you about how we're executing our plan and the value opportunity that we think it presents.

So our financial objectives are centered around the opportunity to generate sustainable, organic sales growth that fuels healthy profit margins and enables strong cash flow that we can use to make smart, strategic capital allocation decisions. It's integrated with our strategic plan. And so when we think about how the strategy matches up with our financial objectives, there's a holistic linkage in decisions we make about resource allocation for things like research and development programs, investments in our global supply chain to help continue to support the growth in our business, business development and the types of resources and where we put resources for our field base personnel who are highly trained and sit shoulder to shoulder with the physicians who are treating patients around the world every day.

So regarding sales, we're in this privileged position of being able to address large patient populations, and to have sales growth that's fueled by successful long-term investments in research and development programs. That's what's really generating this organic growth. And ultimately, it puts us in a position where we can have a leadership role that's supported by an

evidence-based value for patients and clinicians and healthcare systems and regulators and all the other stakeholders that are impacted by the work that we do at Edwards.

So in terms of sales, we've had this long run of at least 10 years of double-digit organic top line growth that paused in 2022, and you've heard a lot of the reasons around it, driven by hospital staffing complications and the other interruptions and disruptions that originated with COVID, but we're still working through those headwinds today. We're excited that in 2023, we see a path back to 9% to 12% growth on a consolidated basis. So at this conference, we always do the say, did. So what we said a year ago was, we expected low double-digit sales growth of \$5.5 to \$6 billion with \$120 million of negative impact from FX. Margins of 78% to 79%, and EPS of 250 to 265.

Well, it turns out, we think now will be at the low end of the new range of \$5.35 billion to \$5.55 billion, with a \$270 million negative impact from FX. So if you break it down, we got about \$150 million more in negative drag from FX, or about a third of the miss from the midpoint of our original range of \$5.75 billion to \$5.3 billion. The other two thirds was shortfall in revenue from especially TAVR and some of the other business units as well.

Our adjusted gross profit margin was around 80%. It was lifted by FX. It was not lifted, especially by any changes we made in the way we're operating the company. But due to the hedging program that we have in place, both with financial hedges and natural hedges, we got this lift in gross profit margin that will largely go away in 2023. I'll talk more about that in a minute.

So here's what's underlying our 2023 expectations. We're assuming a gradual recovery, gradual recovery in hospital staffing and a resulting improvement in procedural volumes. We're expecting growth across all of our major regions, the U.S., Europe, Japan, and the rest of the world. At current rates, we're now expecting about a \$100 million headwind to sales in 2023. So using 2022 rates applied to our sales forecast in 2023, we think it reduces sales by about \$100 million. This is less than what we said six weeks ago on our third quarter earnings call. At the time, we said it's going to be about the same as what we're forecasting in 2022, but FX rates have changed dramatically in the last six weeks and that's the reason why we're now expecting just \$100 million headwind.

We are expecting an accelerating growth rate during the course at 2023, so think lower sales growth year-over-year at the beginning of next year than in the latter part of next year. This largely has to do with just the year-over-year comparable. So the first quarter of 2022 ended up being a pretty strong growth quarter and it makes the bar a little bit higher for demonstrating year-over-year growth rates, the first quarter of 2023. Overall, 9% to 12% growth, or \$5.6 to \$6 billion in sales. For modeling purposes, we'd point you to \$5.8 billion on consolidated sales at today's exchange rates.

Longer-term, in TAVR, we're talking about low double digit growth rates fueled by the continuing march that we see towards this \$10 billion total addressable market in 2028. So in TAVR, we're expecting similarly growth across all major regions in 2023. The launch of SAPIEN 3 Ultra resilia is going to be a big factor in our growth in the U.S. in particular in 2023, so we're excited about that. And we're anticipating stable average selling prices on a global basis and share positions on a global basis.

So in transcatheter, mitral and tricuspid therapies, you heard Bernard talking about our focus on excellent patient outcomes. So we think that there's going to be a healthy lift to sales in Europe and in the U.S. as we introduce PASCAL here, but we're really focused most importantly, on building the solid foundation and confidence building experience for physicians by getting great patient outcomes. We're expecting EVOQUE tricuspid in Europe to be approved late next year, we're disappointed that it was not improved this year. We talked a little bit earlier about MDR, and the impact and uncertainty that's created around that approval timeline, but we're really excited about EVOQUE and the experience that we've seen so far and the impact that we think it will have on patients.

We expect to complete enrollment in the ENCIRCLE trial for SAPIEN M3 in 2023, and we're going to continue to advance these pivotal trials that we laid out earlier this afternoon. Overall, we're expecting \$160 to \$200 million in sales at today's exchange rates, think \$180 million for modeling purposes. In surgical structural heart, we talked about resilia and the importance that has in helping to grow this business both for aortic valves and for mitral valves. We're expecting another year in 2023 of mid-single digit rate growth, or \$870 to \$970 million.

Similarly, in critical care, we're expecting mid-single digit growth fueled by this continuing improvement in smart recovery with this leading predictive technology. It's unusual in the critical care field for there to be much data generated. And Katie and her critical care team have been doing just that, and we think it's really going to help seed growth in the years to come as new clinical data gets introduced for physicians and their patients.

So the second element of our financial focus and expectations is around profitability and continued healthy gross profit margins, despite the fact that we've got this FX benefit from 2022 rolling off in 2023. So strong growth profit margins. We're going to continue to be funding our field based organization, so that hits us on the SG&A line. We're investing aggressively in R&D, both in clinical trials and the actual research that goes on before we launch clinical trials. And at the bottom line, or towards the bottom line, we're going to continue to maintain a smart and efficient legal entity structure and tax structure when we make changes to the company.

Our gross margin is going to be unfavorably impacted, as I mentioned before, to the tune of about 300 basis points in 2023. So last third quarter earnings call, six weeks ago, I said 250 basis points. That's increased based upon what's happened to rates, to where we think now it's a 300 basis point deduct from gross margin at today's rates. Obviously, rates have been moving

around a lot. We're trying to give you an updated information, and that's what it looks like today.

Overall, we're expecting 76% to 78% gross margins. We'll get some lift from product mix and the faster growth of our higher profitability products, as well as some of the operational efficiencies that we're continuing to see as we expand and grow the business across our current seven production facilities, and we're continuing to add capacity in the years ahead. Negatives in addition to FX, are just wage and materials inflation. For Edwards, it's not a big number, but it's a factor that we're watching and we're managing very carefully. We're really proud of our global supply chain, both within Edwards and the partners that we have outside of Edwards, in not just managing inflation, but keeping our supply chain intact and making sure that we can have finished goods on the shelves available for physicians and their patients around the world. Despite all the disruptions to other supply chains, we've fared pretty well.

In terms of operating expenses, SG&A and R&D in 2023, we're going to continue to see benefit from just leveraging our scale. As the company grows globally, we get benefits from being able to spread the investments we make and what it takes to run the company across the board. We are seeing the same FX impact that's going to be a negative to our operating margin in 2023. Again, think about 300 basis points. That'll take our operating margin to about 30% for 2023.

We're also going to continue to make investments in clinical trials. We expect R&D as a percentage of sales to be 17% to 18% in 2023, similar to 2022, and we're excited about the initiatives we have underway to inspire more therapy adoption. So we're investing in going direct to patients, direct to caregivers, direct to physicians. There's not huge numbers in terms of percentage of sales, but it's an important and growing source of investment that we're making in the business, especially to help drive TAVR adoption.

So here's just a walk in our earnings per share from 2021, where we had \$2.22, to this year, we're expecting \$2.40 to \$2.50. Same guidance we provided on the third quarter earnings call. You can see next year, the walk goes from \$2.40 to \$2.50 to just low single-digit growth to \$2.45 to \$2.60, think low \$2.50s at the midpoint of the range. A lot of this is FX almost entirely offsetting all of the profit from growth. A lot of the FX is a carryover from 2022. So 2022 profit was boosted by having our hedge program in place, and we're going to feel the effects in 2023. This is exactly how the program is designed to work. We have not figured out a way to outthink, out skate the global FX markets. All we do is try to lock in and protect the guidance that we provide every year at this investor conference, and that's the reason why you see this big headwind hitting us in 2023.

So third financial objective is capital allocation, and we're really focused on continuing to generate robust cash flow. It supports our global capacity expansion. So investments that we put into our plant and facility network around the globe, and it helps us fund acquisitions. It helps us fund external growth and we'll talk more about that in a minute. And ultimately, we're

really passionate about returning capital to shareholders through share repurchase, which we've been doing very aggressively in 2022.

So for adjusted free cash flow, we're projecting \$1 billion to \$1.4 billion in 2023. This year, we're not providing an update on our free cash flow for by 2022, but year-to-date through the third quarter, it was about \$800 million. So share buybacks. So we've done two accelerated share repurchases in 2022. We've also been doing other repurchase activities that got us up to about \$1.7 billion in total share repurchase.

You can see in the last 10 years, we've taken on a split adjusted basis, our shares outstanding from over 700 million to now over 600 million. So we've taken about 100 million shares out of the market through ongoing consistent share repurchase activity, and we think it's been a real value creator and we're going to continue to be active in share repurchase over time, and opportunistically. And we're really focused on two things. One is offsetting the dilution from our pay for performance philosophy, and the stock grants that are issued to employees. And two, we want to keep bringing in the net shares outstanding. We think it creates real value for shareholders, And so we're going to be doing that on an ongoing basis.

So we're also investing capital for the future. Our capital expenditure forecast for 2023 right now is about \$300 million. And it really falls into a couple of buckets. More than half of it is for manufacturing redundancy, manufacturing resiliency and capacity expansion. We also invest significantly in our infrastructure. For those of you who have been to our Irvine headquarters campus, you've seen we've invested in a lot of new laboratory space where our research and development engineers continue to do their magic. And so we're going to continue to fund our capacity to be able to innovate and design new technologies for the years ahead. So that's a little bit of just a snapshot of where we're pushing capital into the business.

We are very active in portfolio management and business development. We don't talk about a lot of the acquisitions we do because they're generally small, and they're a competitive sensitivity. So we don't really want to advertise all of our actions that we're taking. Usually, we're looking for companies that, number one, fit our strategy. Just because we have cash on the balance sheet does not mean that we're changing our focus on structural heart and critical care medicine. And so that's where we really focus our attention in terms of our external growth supplements.

We look for generally smaller tuck in acquisitions. Most of the types of businesses that we can buy are small, early stage, pre-revenue, pre-approval, sometimes pre final product design, and it fits well as a complement to what we do internally in R&D. We're also continuing to look at our portfolio of products. And when we see products that either have become non-strategic, or where the profitability profile and potential is more limited, then we'll look for a way to try to reduce that element and take products and codes out of our business. We also look carefully about our R&D programs and think carefully about where the real growth opportunities are for

new initiatives that we underway and we're pretty disciplined about making sure that we are managing that on an ongoing basis.

So just a summary of guidance. I won't go through this, but it's in your books, if you're interested. It captures what was in the press release today and the other slides that you've seen so far. Before I wrap up, I just want to summarize some of our long-term expectations and how we're running the company. First and foremost, we're expecting the opportunity in the markets we serve to double from \$10 billion to \$20 billion. Now, I want to pause there for a second because one of the questions we've gotten is, hey, with the shortfall in sales in 2022, does that change the trajectory of your sales growth between now and 2028? And the short answer is not really.

So we missed sales, excluding foreign exchange by about \$250 million in 2022, relative to the midpoint of our original guidance. \$250 million in one year doesn't really change the overall picture and opportunity between now and 2028. The second area where we're focused longer term is on operating efficiency. We have the opportunity to expand our margins. And we think about this carefully because if we wanted to, we could boost our margins pretty quickly by cutting down on R&D, slowing down the investments we're making in our field-based personnel to support the growth of the company, and we've just chosen not to do that.

We think the opportunities are so important ahead of us that we should keep investing and keep funding these programs. We think they're going to pay off over the long-term. But we do have an opportunity to toggle margins, and we're continuing to look for ways that we can do that when it's appropriate.

Finally, in terms of earnings, we're going to see a tax rate this year that is comparable at the midpoint to the tax rate we're seeing in 2022. So next year tax rate similar to this year tax rate, but at probably best case, it's neutral. There's probably going to be upward pressure on that over time based upon some of the legislation that's being discussed right now. Earnings per share, again, repurchase activities combined with all the other actions we're taking, we think earnings per share has an opportunity to continue to grow and grow faster than the top line, at least that's the model.

So to wrap up, you've heard about the linkage between our financial objectives and our strategy. And overall, I can say, Edwards is a purpose driven company. We're on a mission to change the way medicine is practiced, and to help patients in need. And we think we have a bright future ahead of us that's going to benefit patients and all of the other stakeholders and shareholders that we serve. With that, Mike, I'll turn it back over to you to wrap up.

Michael Mussallem

Thank you. All right. We're running a little bit behind, so I'll catch us up because I want to make sure that we have time for a good robust Q&A in typical Edwards fashion. We like to deliver on our commitments and stick to our schedule. So we'll do exactly that. Hopefully, you enjoyed all

the presentations that came in front to give you more visibility into our businesses, and also our financials.

Big picture for us, our strategy is unchanged. It's not because we don't take a hard look at it, because we do that. Every year, I mean, we really turn it upside down. We work hard with our board of directors to say, is this still right? It feels good but should we change this? And we just come away as committed as ever and say, you know what, this is the right strategy. Let's innovate, let's lead, let's stay focused. And so we're totally committed to that principle. We think it's differentiated, and we think it's a success formula. We really believe in that.

'23 is going to be a year of strong growth. We think it's going to be a really nice year. I won't go through it more. Scott took you through the details, and you saw what was in each of the businesses. I could certainly lay that out in more detail, but '23 will be a good year. But we don't just look at the next year ahead, as we talked about before. We're out there on a pretty significant horizon, but always stay mindful that we should be delivering in the short-term as well as the long term. This isn't, hey, you have to wait till someday to see results. You'll see results now.

Our board is pretty special. I'm really proud of our board. They are highly engaged. These are super experienced people that are committed to our success, and they do everything that you would want from a board, from support us when we need support, to challenge us when we need challenging, and really engaging with us. They know our leaders. They know our strategy. They go deep. They bring all their experience. And they also stay on top of the leading practices and make sure that we really perform to the expectations of our shareholders and all the other various constituencies that we feel an obligation to.

Sustainability is not a separate subject inside Edwards. We don't have a separate over here, we kind of have it just integrated into our strategy. As Scott talked to us as a purposeful company, that's very much the case. And so it's just integrated into everything we do. We get recognized externally for our sustainability practices, but that's not why we do it. It kind of comes natural for us, and we're going to continue to do that. And it'll be a normal course of business and my own performance measures and the performance measures that the executive team incorporates achieving all of our goals to continue us to be a highly sustainable company.

So we're fortunate to be a successful company that has nice profitability, and it gives us the ability to be able to give back. And that's really important to all of us. Our employees love the fact that we give back. When we get meetings together, often, we'll have a charitable theme to the meeting. And we'll do something with that as the team building activity that we'll do. We have a signature program that we call Every Heartbeat Matters, that has a goal of improving the lives of two and a half million additional underserved structural heart and critically ill patients by 2025.

It got harder with COVID to accomplish this. We've got over 50 partnerships to do this, but we're going to do it. We're going to achieve this goal. I'm very excited about that. And we also have a simple message to employees. Wouldn't it be great if every single person in the company did one thing charitable each year, something that you care about, not something that the company cares about, your own charity? And they embrace that and go for it. And the last time we surveyed, over 85%. So it's sort of in the DNA of the company.

So I'll just close by saying, I think that the company is poised for a very bright future. Why? Big population that needs us. Right? These patients that are suffering from structural heart disease, the critically ill and beyond, they don't have great solutions yet. We can make a difference. If we can design procedures that you can do in a short period of time, an hour or two and get people home in a day or two and change the course of their lives, and do it cost effectively for the system, we create a tremendous amount of value, and we focus on those large populations.

We're fortunate to have built credibility and trust that it gives us the privilege of being able to innovate and have people take us seriously. We've got this incredible culture where people come because they say, yeah, I like the pay and the benefits are nice, the facilities are nice, but what makes me feel good about my job is that I know I'm helping patients around the world. And that just is a real glue for the folks that work at Edwards Lifesciences.

We got a pretty special R&D team. Not only are they very bright people, but they're innovators. They go for it. They dream big. They reach high. You have to learn to deal with failure along the way, because that's part of it when you reach high, but we've got this nice culture that really puts us in a position to be able to accomplish some things that might have been unthinkable not long ago. And our formula for growth doesn't count on doing some kind of a brilliant acquisition. It's still organically create opportunities and turn that into real growth for the business on a long-term basis.

And when I look ahead, I feel like the best days are in front of us. We're sort of entering a new era of structural heart innovation. I mean, when I look ahead, I say, wow, this is good. We're in sort of this golden age, where it was what we did in the past, we're going to almost look at as primitive compared to what we're able to do in the future. And so I'm super excited about what's in front of us.

So with that, we're going to take a short break, set up for some Q&A. So the break won't be long, and then we'll jump right in. And we'll have, a matter of fact, the whole team of speakers here to join me. Thanks.

Mark Wilterding

All right, everybody. Welcome back. I hope you enjoyed the afternoon. A lot of good information. We've got an hour now for Q&A. So it is a little after 3:20. We'll run to about 4:20. I mentioned earlier, we've got Kim (INAUDIBLE) on this side with a microphone, Linda Wright on this side with a microphone. We'll do our best to get to everyone's question. To the extent you

could limit it to one question, and one follow up, I think we'll have a good chance to do that. So who wants to kick us off? Robbie Marcus.

Robbie Marcus

Thanks. Robbie Marcus, J.P. Morgan. First, Mike, congratulations on retiring, excellent career, well done. And Bernard and everybody else moving around, congratulations. Maybe it could start off on the guidance with TAVR. And it's been a tougher second half. It's still growing, but not as well as expected. We're seeing an acceleration in the guidance throughout 2023. What gives you confidence that you will see an acceleration, return to double-digit growth in 2023?

Michael Mussallem

Yeah. Well, why don't I start and then Larry, you can talk more about just the big drivers. But just in terms of the guidance itself, we feel like if you look over the last two year CAGR, three year CAGR, four year CAGR, it's consistently 9% to 12%. The last couple of quarters in 2022 are not indicative of what we think the growth is going to look like as we model out 2023. The first quarter is kind of a high bar, as I mentioned before, because of the first quarter of 2022 being a high growth quarter. But we've got a lot of confidence that we're going to return to that two and three and four year CAGR as we get into next year.

Larry, do want to talk a bit more about some of the drivers for that?

Larry Wood

Yeah. I think, as I talked about, patients are--we're seeing echo's going up. We're seeing a lot of the diagnosis starting to increase in the system. And we do believe that those patients are going to have to start flowing through the system. I think there could be a little--maybe a little bit of a backlog. It's hard to quantify, but we also are going to have really a full year of (INAUDIBLE) launch in the U.S. We're also going to be launching it in Japan. And we just feel like some of these COVID headwinds are going to be largely behind us. And staffing, we are seeing that improve over time. And I think it's a combination of all those things that give us confidence that we're going to be in that 9% to 12% range globally.

Robbie Marcus

Okay. Maybe just a quick follow up. I forgot to ask. Any differences geographically we should be considering? And as we think about the TMT guidance, that also assumes a pretty big pickup. how much of that is the launch of PASCAL in the U.S. versus continued European performance?

Bernard Zovighian

Thanks for the question. So obviously, we are in a presence in Europe for quite some time now. So we are--the majority of growth will come from Europe, but also, the U.S. is going to be a good and important growth driver next year. We are going to expand. We are just starting. We are still training the team, training physician, but we have greatest aspiration for the U.S. So think about more Europe than the U.S., but U.S. will be important.

Mark Wilterding

Larry Biegelsen.

Larry Biegelsen

Thank you. Larry Biegelsen, Wells Fargo. Thanks for taking the question, and I'll echo the congratulations to Mike and Bernard and the whole team. Mike, really, truly amazing 20 plus years. So for my question, Larry, I guess I'll ask on the TAVR share question. It does look like Medtronic took some share in the third quarter. What are you assuming for 2023 for share? And what do you think happened in the third quarter regarding share?

Larry Wood

Yeah. I think it's important to remember our quarters don't line up exactly. And I think we see slight fluctuations quarter-by-quarter, but I don't believe there's been any share shift that's that's happened over time. And I think as new competitors come in over the longer period of time, we do model a little bit of share erosion. But overall, if you look at our history, we've been pretty solid about holding on to our share. And we're really excited about our portfolio and our product launches, and I think we feel great about our share position. And I don't think it's going to move significantly, so it's not a big concern of mine.

Larry Biegelsen

And just one follow up for Bernard. Just Abbott is probably only to present the pivotal TRILUMINATE data in the first half of next year. They said they're going to file. How does that impact your ability to, if it's positive, to enroll your tricuspid trials for TRISCEND II and Class 2TR? I didn't see anything on that on enrollment. Thank you.

Bernard Zovighian

Yeah. Thanks for your question. So hopefully, the data that will present will be positive. There is all the time, a gap between when you present and when when you get an approval, especially when it is the first device for (INAUDIBLE) disease state. So this is what we are assuming here. So if it is positive, it will increase the enrollment of a Class 2TR study, which is a positive, positive for the field, positive for patient.

The TRISCEND II study with EVOQUE is probably one of the fastest and (INAUDIBLE) study ever, ever in the company and probably ever in the field. So we are aiming to complete the study in mid next year. And the two devices are not necessarily treating the same patient population, so I don't see any any issue here, more of a positive than anything else.

Mark Wilterding

Vijay Kumar.

Vijay Kumar

Thanks for taking my question. Vijay Kumar from Evercore. And congrats to all of you. Maybe my first question here on the management transition. Mike, Larry and Bernard, for all three of

you. The transition is happening at a time when people are questioning on TAVR outlook. Is the market penetrated, saturated? Historically, when we've seen this for other companies, there have been more transitions in the leadership team. So Larry, Bernard, I know you guys work well together. Going forward, what can you say to give comforting measures that there won't be any more transitions, any impact to the business here?

Bernard Zovighian

Want to start?

Larry Wood

I don't know. For me, personally, I'm in the job that I want. And as you get older--when you're younger, you just kind of chase titles and you chase those sorts of things. And as you get older, you have to start thinking about what do you really enjoy doing? And what do you love doing with your life? And I love being with the teams. I love being in the cath lab. I love being with our clinicians and working on groundbreaking trials, and I love doing all those things. And these two schmucks never get an opportunity to do any of that stuff, because they're out doing other stuff. And so I think I kind of have the best job in the company in terms of what I get to do. And I'm super excited about having my responsibilities expanded. And Mike and Bernard and I have spent a lot of time together talking about it. And I don't think I can add any more value to the company than I can in my current chair. And I've been here 37 years, and you're probably not done seeing me at these things every year.

Bernard Zovighian

So let me tell you, how do I feel about it? I feel very confident for many reasons. First, Mike and I, we are going to work in tandem for quite some time here, until May next year. And then Mike is not going anywhere. He will be the Executive Chairman. But that's why I think it is super important for me to have someone like Mike helping me with this transition.

Two, is we have a great company. When I joined the company eight years ago, I was amazed, and I am still today. We have great people, amazing culture. The way we are innovating is pretty unique. The ELT, I have seen many leadership team in my career, that's probably one of the best that I have seen. So I look at all of that. We have great foundation. We have an amazing transition.

And then I think about--let's talk about Larry again, which is very important to me. Larry is an amazing innovator. The TAVR story is a unique story. Nobody has done what we have done with TAVR, and Larry was at the beginning of it. So I think Larry leading two businesses, that's a great win for me. I love that. He loves that. I love it. We need that. So I think it is a great solution for everybody.

Michael Mussallem

Yeah. And so just to the broader point of transitions in companies, and I know it means a lot of different things in different companies, but if anybody even for a second things that I stopped

caring as much, tomorrow, January 1st, May, they got it all wrong. I mean, I'm all the way in. I love this place. I love our team, what we do, what we stand for, and I think we have an incredible executive team. And I really count on the fact that we're going to show that. Right? We're going to show just how strong our team is as time go forward and we're talking about the new era. I'm serious about that, is a new era coming.

Vijay Kumar

It's helpful. Thanks. So I think Bernard, Larry just gave you a compliment. He said, younger people chase title, so there you go. One on finance for you, Scott. Free cash flow, it's been flat versus fiscal '21 levels. And when I look at your margin trade, FX is 300 basis points impact, but 30% off margins in place. There's no leverage here in the operating margin. With 800 TAVR centers, there should be some SG&A lever. So where are those investments going in SG&A? Thank you.

Scott Ullem

So a couple things. You're right. The operating margins in 2023, we think will look similar to 2022, which is similar to the way it's been for the last handful of years. This is intentional. We've just seen such big opportunities and TAVR and in TMTT in particular that we feel like we need to fund them. And fund them comes in the form of funding R&D clinical trials, and the eight clinical trials we talked about, but also funding the growth with people in the field who can really help train physicians, support physicians, and make sure that patients are getting the outcomes that we all desire.

So we don't have to run the company that way, but we think it's the right way to run the company because our goal is not annual margin expansion every single year. Our goal is organic, sustainable top line growth. With that, we do believe over time, we are going to see an expansion in the operating margins. You mentioned cash flow. So part of this is when you don't have expansion in the operating margin, you're not going to have a whole lot of expansion in cash flow. But we've got another headwind, which is the section 174, where we now have to capitalize R&D expenses and get the benefit of those tax deductions over years rather than all at once, which is the way it used to work. It may be that 174 gets addressed by this Congress. We don't know yet, but that's one of the reasons why we're a couple hundred million dollars shorter in cashflow than we would otherwise be.

Mark Wilterding

Joanne.

Joanne Winch

Thank you very much. Joanne Winch. There's something you said earlier that said, it's a big population that needs us. What's happening to these patients today? Are they passing away? Or are they a backlog? And I'm having a really hard time trying to understand if physicians are seeing this big population, why they're not motivated or why they're not moving? Or what are hospital's doing to address this?

Larry Wood

Yeah. It's a great question. It's probably one that frustrates us more than anything. We know the patients with aortic stenosis. If you go all the way back to the partner one trial, which were very sick patients, but there was a 50% mortality rate at one year if you had a severe aortic stenosis and it went untreated. And you could argue in lower risk patients, maybe that's two years, but patients don't live well with severe aortic stenosis, and we know that and it's clear in the literature. But I think a lot of it is this ascertainment of symptoms and going all the way back to the guidelines, that you have these people with this severe disease, but then they're doing this mental gymnastics about whether they have symptoms, and whether their symptoms are attributable to the valve disease and all of these other things.

And the patient pathway, it's not like you go see the interventional cardiologist, and he manages your whole cycle of care. You're at a GP and then you go get an echo, and then maybe you get referred to a GC and that doctor watches you for a while and before they ever refer you to a heart team. And one of the things that Brian said in the video that's really critical is once a patient gets an any intervention, we have all the metrics in the world about what happens to them, how long they live, what the Kaplan Meier curve looks like. But from diagnosis to treatment, we have literally nothing.

And that's really what we're trying to accomplish with the AHA initiative, is creating metrics that hospitals are measured to, that says from the time a patient gets a definitive diagnosis, how long does it take for them to get the appropriate guideline indicated intervention? And if we could get that as a quality metric that hospitals had to report on, and that was a 90 day metric, it would be an absolutely fundamental game changer to help patients move through the system.

Michael Mussallem

Yeah. And I might just add a little bit to just say, I mean, when you think about the different parts of the healthcare system, there's flaws along the way. The primary care physician, often, because what Larry said, this ascertainment of symptoms, if the physician sees this as old age, as opposed to aortic stenosis, they don't act on that. They say, well, of course, you aren't able to walk as far or breathe as well as you used to do. That's just old age. And they misdiagnose, not through any fault of theirs, it just, it's not obvious to them.

In general cardiology, it's amazing the difference between general cardiologists. We see general cardiologist that routinely refer to a heart team as soon as they see aortic stenosis. We have others that say, you know what, let's keep an eye on you. Come back next year, we'll take another look. Right? And then when you get to the treaters, they actually don't have a great understanding of what's upstream. The treaters themselves, the interventional cardiac--much like the surgeons that we dealt with two decades ago, when we asked them, hey, are you treating all the errors? Oh, yeah, I never turn anybody away. They just don't have a good idea who never makes it to their door. And so it's a combination, but through our market expanding,

clinical trials for the education efforts, etcetera, we're going to make a real difference than that, and it we'll gradually improve.

Larry Wood

Our first indication is for inoperable patients, which was a population that didn't exist. And it turned into about a billion dollar opportunity for patients that didn't exist. I think the one last thing about that, and sorry I'm so passionate about it, but early TAVR is the other thing. And we got to get to the endpoint and all that. But if we could take symptoms out of the equation for the treatment of this disease, it would completely change how patients flow through the system, because we'd just be treating the disease rather than doing all these other medical--

Michael Mussallem

--so you just look for an echo that says that the valves closed, and you don't try and--

Larry Wood

--it turns into track and field instead of Olympic figure skating.

Joanne Winch

Okay. Just a quick follow up for Scott. 30% operating margins, but you're going to invest, but you're going to expand. Help me reconcile those, expanding operating margins over what time period? And what do you think you can get to? Thank you.

Scott Ullem

So I mean, a lot of this is just when these investments that we're making right now in clinical trials turn into products and therapies that become commercialized. Longer term, we expect our top line to be growing faster than our expenses, and that's, of course, how we're going to get margin expansion. What we don't want to do is curtail the opportunities we see right now for investing in long-term growth in order to demonstrate margin expansion in 2023.

So we're going to keep the pedal to the metal in R&D. We're going to keep going aggressively at it, but we do believe that over time, as the top line grows faster than the expenses, that we're going to see margin expansion. And it's probably going to come more at the operating margin than it does at the gross margin. Sitting here in high 70%, that's pretty high for a med tech company. Operating margins is also high, but we think that's probably more where it'll show up over time.

Michael Mussallem

And there's real opportunity. And I'll just pile on a little bit. So for example, our supply chain is very strategic and very long-term focused. And so they've got a lot of ideas about automation and end sourcing and goes on and on, but potentially have margin improving opportunities. Now, at the same time, we're always introducing brand new products that are very novel that maybe don't have the margin profile, so there's some natural tension there but we've got some helpers along the way. Yeah.

Mark Wilterding

Pito Chickering.

Pito Chickering

Thanks. Pito Chickering, Deutsche Bank. Follow up to Joanne's question with sort of a slight twist here. You talk about ageism as an issue for patients not getting treated. Just make sure I understand that. These patients are diagnosed with AS and the doctors were refusing to treat them because of their age, or the moderate, or they simply aren't being diagnosed because of their age?

Larry Wood

No, I think what we're largely talking about are people that are in the system, because where we track is from diagnosis to how long it takes them to receive therapy. So I think the diagnosis happens. I think people order the echo's for the patients to understand it. I just think there's a bias in the system. And we see it--we probably see it even more in Europe sometimes, where they'll literally say, this patient is 80, should we really put them through this procedure and deploy this expensive technology when they're only going to live another year or two?

And that's what's in people's minds about how long an 80 year old is going to live, because they look at average life expectancy. But it's a very different equation if you take a look at what the life expectancy is for someone who reaches the age of 80, and that's where you get to that nine year point. And so I think there's just a tremendous amount of education that has to be done on this, but there very clearly to me isn't bias against treating elderly patients as aggressively. Whereas I think if a 65 year old comes in or a 60 year old comes in with that same disease, there's a real drive to get that patient treated very quickly, and we see that in the data.

Pito Chickering

Okay. And then the follow up there is as you think about growth accelerating into 2023, is this being driven primarily by possible staffing issues getting fixed, or is it primarily from getting the people who've been diagnosed with AS, or that aren't being treated into treatment?

Larry Wood

I think it's a little bit of a lot of things. I think we've got to get patients off the sideline. I think the last couple years, certainly, there's been more patients probably waiting or reluctant to go seek care, and so we need to get that all working again. I think we are seeing gradual staffing improvements at the hospitals, and we are seeing them build capacity back into the system. It's not like we've gone down from where we were pre-COVID. We've been growing. So the hospitals have been building capacity, just not as fast as what they were doing pre-COVID.

So I think we're just going to start seeing some of that return, some of that normalcy coming back, and patients moving through the diagnosis and treatment funnel more cleanly. I think what's happened is there's these COVID flare ups that somebody might be halfway through

getting screened and then they sort of drop out again, and then they have to kind of get back in line and come back through again. And hopefully some of that stuff starts to dissipate. And we tried to factor that all in pretty carefully on a global basis and that's how we got to our guidance.

Michael Mussallem

Yeah. And there's no perfect prediction of what's going to happen, but I get the privilege of interacting with CEOs of hospital systems on a pretty routine basis and they're not doing well right now. The combination of inflation and the fact that they have staffing issues, that means that they can't do all the procedures that they'd like to do, and we're in a fee for service system. And so they're highly motivated to fix those staffing issues so they can do the procedures, so they can get paid, and get their system back in balance. And these are smart people that are going to make it happen. And so they built nursing programs. They changed the way that they do their benefits, and so forth, and I really think it's going to gradually improve over time.

Mark Wilterding

Travis.

Travis

Hey. Good afternoon, and thanks for hosting the analyst day. You gave--I guess you reiterated the guidance for 2022, but maybe give us a bit more color on how Q4 is shaping up some of the flu, COVID, RSV staffing trends. And U.S., OUS, I'm assuming the quarter is not just all driven by currency getting better. There's probably some underlying trends there better. So just any color you can give on Q4 would be great.

Scott Ullem

I mean, currency's gotten a little bit better, but not enough to really change our guidance that we provided. We gave guidance on October 27th. So right in the middle of the quarter, or a few weeks later, we're just not going to get into the week-to-week, play-by-play by country by business unit. What we will say is, our guidance is unchanged. So the guidance we provided back in the end of October is still the guidance for Q4.

Travis

Okay. That's fair. And then for next year, you said pricing was stable, but you said there's a \$1,500 markup on, I think it was SAPIEN with resilia. So I wanted to make sure I understood those comments and how you're baking in pricing and for next year. And then also, make sure you had a little more color on the X4 trial that you stopped.

Larry Wood

Yeah. So a couple things. When we say pricing is generally stable, we're talking about that on a global basis. And because there's reimbursement changes in certain markets in Europe and other things that happened, this sort of offsets that. And we still do the volume discounting

that we do, but we are absolutely going for a price increase with SAPIENT 3 Ultra resilia. The list price changes \$1,500 And so that is factored into our guidance as well. And we'll be rolling that out throughout the year. When we roll out a product and there's no price increase, it just goes on the shelf immediately. When there's a price change, it has to go back through the contracting process, so that also takes time to get through. So we're going to be launching it all throughout the year as hospitals sign the contract, and as hospitals move forward. So that's that.

On the ALLIANCE trial, I want to be as clear as I can on this. We love the platform, and the valves perform spectacularly. And this trial was enrolling extremely well. So we were really pleased with how the trial was going. But the bar that we've set with SAPIEN 3 Ultra and now SAPEIN 3 Ultra resilia is really, really, really high. And we see an opportunity right now to improve the user experience. And when it comes time that we enter the market with X4, it needs to perform at a really high level.

And one of the things just to note too is, we didn't do an early feasibility trial with X4. We went straight into a pivotal trial, (INAUDIBLE) based on an order of bench testing and based on all of our things. And we just had a learning when we got into clinic but I'm extremely confident that we're going to be back in trial next year. The changes we make are going to be minor, but it's not something where it's affecting the delivery of the valve or the valves not performing right. It's just a change that we think we can address us relatively quickly. The problem is anytime you pause a trial, and you have to restart it, you have to go back through the IRB review process again. You have to get FDA ID approval again. And so there's just a time lag there, but we'll be back in clinic next year with this platform.

Michael Mussallem

Yeah. And it's fair to add that the X4 has a lot of novel features to it. I mean, it's really remarkable. And it took some courage to jump directly into a pivotal without an early feasibility study, but we said, hey, let's go for it, we have a lot of expertise. But when we learned some things and say, we can make it better, we said, you know what, a slight pause, that's absolutely worth it. Right? It's going to pay off well in the long run.

Larry Wood

Well, and remember too, we're just launching S3-UR are now, so it's not like we're in this portfolio wasteland where we have no new products or anything. So we really have the benefit of time that we can take the time and really make sure we get it optimized.

Mark Wilterding

Josh.

Josh Jennings

Thanks, Mark. Josh Jennings from Cowan. I was hoping to o ask about the U.S. TAVR remark. And just three buckets of smaller segments you could comment on Larry, being for '23, but also

through 2028 as well. But just thinking about TAVR and SAVR, TAVR and TAVR, and maybe even low risk bicuspid patients and those coming off with smaller base, should we be seeing significant growth contributions from those three buckets? And then I just have one follow up.

Larry Wood

Yeah. I don't know if I can quantify and read directly. But I will say, a significant part of our business is non-native aortic TAVR. We do a lot of surgical valve in valve. Increasingly, we're doing more TAV and TAV. But the other thing that we do is, people forget, we do mitral valve and surgical valves. So we fix failed mitral valves, and that's an indication indication for us. We also do rings, so that's another thing that they were able to do. And those are all approved indications for us. And we also have pulmonic, which we're growing with Alterra. So there's a lot of things we can do, but those alternative segments are all growing and that's something that we benefit from as well.

Josh Jennings

Thanks for that. And just to focus on just Class 2F. It wasn't emphasized today, and just wanted to understand why not. And just has that trial design evolved similar Class 2D? Is that a Bayesian design now (INAUDIBLE)? Thanks a lot.

Bernard Zovighian

No, thanks for all the questions. So first, let me tackle the second question. Every trial is different. You have different, obviously, statistical analysis, endpoint, all of that. So you cannot expect that what we did with one trial will be translated to another trial, correct? We are trying to be aggressive, strategic, for sure, but we want to bring world-class evidence. So I would not expect this on 2F.

With regards to why not talking about it is, look, I talk about the one that we are going to achieve, big milestone in 2023, EVOQUE, competing in (INAUDIBLE), (INAUDIBLE) next year. Class 2D, in my mind is going to be very meaningful. You have a full court, one year. So this is-- and free (INAUDIBLE). So I try to focus on what's going to happen next year. 2F is going well. It is an important study. And I'm going to talk more in the next quarters.

Mark Wilterding

Chris Pasquale.

Chris Pasquale

Thanks. Chris Pasquale, Nephron. Bernard, a couple of questions for you. We've talked a lot about the slowdown in the U.S. TAVR market, but the U.S. tier market has actually been even more sluggish in '22. You're now a participant in that market. Have the causes of the slowdown there been the same as TAVR or different? And what do you think that market grows in '23?

Bernard Zovighian

Yeah. I would say a little bit the same and there is also some differences. So the same, obviously, the COVID, the staffing, obviously, it is impacting all of this space. What's different, though, is the clinical evidence. In TAVR, we have so many evidence, solid evidence for years. And we were (INAUDIBLE) big leader in that space. For mitral, like I said, very little evidence in the past 10 years, and some of the evidence were mixed, which is why I'm very excited about Class 2D, even if it is just for the DMR patient population. But physicians are looking at Class 2D and they are saying, look, it is contemporary data with both devices, and it is working very well.

The tier outcome is better than what it was five years ago, three years ago. So I am truly hoping that this will give confidence to the physicians, to the community and to patients. So I think that is changing. This is what is impacting the mitral space in the U.S. and in Europe, to be fair.

Chris Pasquale

Yeah. That's helpful. Thanks. And then you talked about growing tricuspid adoption in Europe, had some great data in London valves. Can you ballpark for us just how big a part of the European business tricuspid is at this point versus mitral, because we tend to think of that as a mitral business, but it sounds like you're making more progress on the other position?

Bernard Zovighian

So for sure, it is still a small business. We don't have the same base than mitral. Mitral (INAUDIBLE) in Europe approve for about 10 years, or eight years or 10 years. But we see a growing interest. Physician are calling us to be trained, to start tricuspid activities. So we are very impressed with the ramp that we see in tricuspid. We are pleased with the kind of outcome physician can achieve with tier devices in the tricuspid disease position. So promise, a lot of promise and it is exciting.

Mark Wilterding

Rick Wise.

Rick Wise

Rick Wise, Stifel. Bernard, doing a bunch of recent doc calls lately, PASCAL has come up again and again, very positively. And just really strong positive physician reaction. Could you talk about your commercial initiatives in the U.S.? And it seems to me, this is one of the areas that could actually be more at the upper end, because of the kind of reaction I'm hearing. Is that a reasonable thought?

Bernard Zovighian

Yeah. No, let me--thanks for the question. Let me start with the first with first (INAUDIBLE) technology itself. Look at what we have done. As a company, we know how to do that, the way we are innovating. We launch with PASCAL (INAUDIBLE). We came up few months later with (INAUDIBLE) and then a year later with precision. This rapid evolution of a technology, being able to respond to physician feedback, to make the technology better all the time. And we have already ideas about the next gen PASCAL.

So obviously, we have, like you said, solid platform. PASCAL Precision today is differentiated. In the U.S., we want to be careful. In my mind, it is all about excellent patient outcome from the beginning. Physician, we want to go fast also. And we are the one telling them, look, training is important. It is a tier category, two different devices. Let's take the time for you to be trained, your team to be trained. Imaging is also--

Michael Mussallem

--he's fighting this all the time. So it's routine. They say, hey, I do a lot of the other technology, why don't you just give it to me? I know what I'm doing. Right?

Bernard Zovighian

Exactly. So yes. So it is like I see the potential in the U.S., amazing platform. We are bringing evidence. We are going to be very careful about treating this (INAUDIBLE) the right way and delivering on this promise.

Rick Wise

Great. And by the way, don't demote Larry for calling you names in public. He's a good guy.

Larry Wood

You should hear what we do in private.

Rick Wise

A quick follow up for Katie, if I could. Katie, I apologize for making you the macro person on the panel, but complicated capital environmental, recession, chip shortages, just any sense you could give us. Are things getting better, worse, stable? Are you feeling more encouraged, less encouraged on any of those fronts? Thanks so much.

Katie Szyman

Thanks, Rick. So first of all, we've really taken a strategy to make sure that we don't go on backorder, and we've seen many of the companies going into backorder situations. So as Mike mentioned, we have a very strong global supply chain. We don't anticipate seeing any back orders. And we see some risk, obviously. But so far, as we look through next year, it looks pretty positive, especially on the chip front, which was a risk this past year. And we just took the strategy, like we're going to do everything we can to make sure that our patients are covered.

The question about capital and the recession, people have asked me at the break, are you seeing it? Or are you just worried about it? I would say, right now, we're not seeing a significant change in our capital ordering patterns. Because if you recall, it takes a year, right, when you start the order process to when you actually close. But as you know, hospitals live on their investments and that's really how they fund their capital budgets. And so we're just seeing that as the recession hits, and as the equity markets are down, it may shift. But right now, I think we're in good shape.

Michael Mussallem

Yeah. I'll just add to this. Katie and her team have done an amazing job of innovating, and they really have a lot of momentum going. And I know she spends time talking about capital and there is a component of the business that's capital, but it's the small component of the business. Most of it are actually disposables, and especially now there's more value add within disposables because there are the smart algorithms that are behind them. Most of it is not really so sensitive to capital only. There's a portion of it but not in a way that some other businesses might be.

Mark Wilterding

Adam Maeder.

Adam Maeder

Hi. Adam Maeder, Piper Sandler. Thanks for taking the questions. Maybe just one quick follow up on the TAVR Outlook, the 9% to 12% underlying worldwide growth. Can you just maybe talk about the different geographic assumptions between U.S., Europe and Japan?

Scott Ullem

Well, I'll start. Again, I go back to part of this has to do with the baseline comparison. So we've had pretty high OUS growth in 2022. So it'll be a higher hurdle to get over that. And our expectation is that there may be pressure on the growth rate outside of the U.S., not because the business is not performing well, but because 2022 showed well. By contrast, the U.S. a little bit lower bar, especially in the second half of the year in 2023.

Michael Mussallem

But having said that, (INAUDIBLE) rates outside the U.S. are pretty low for TAVR. Still, by comparison in the U.S., there's a dramatic difference. So we just see international growth rates continue to be probably, overall, a bigger driver.

Larry Wood

Yeah. The other thing I'd say is--and I think the thing that Scott brings up is really right, because there's so much quarter-to-quarter variability this year if you go to different regions. If you look at Q3 in Japan, it got pretty hit pretty hard. But you look next year in Japan, we're going to launch S3-UR in Japan. And we were right in the middle of the low risk launch, or just starting really the low risk launch in Japan when COVID really hit, which made things difficult.

But the other thing is, Japan never got S3 Ultra. They never got SAPIEN 3 Ultra. They were still on the SAPIEN 3 platform. So they're going to go straight from SAPIEN 3 to SAPIEN 3 Ultra resilia, which is going to be a big jump for them, because it has all the benefits, rather than just sort of the incremental benefits of the resilia. So we're super excited about that launch in Japan, and we think that's going to be a driver too. But we really tried hard to factor all that in

but it's hard to talk about the regions because it changes quarter-over-quarter based on what happened the previous year.

Scott Ullem

I'll just add to that. Just when we think we figured out what the model is and cracked the code on what the growth rates going to be by region, we get surprised. And this has happened consistently. But it also gives us confidence in our strategy for TAVR, where having this therapy available now in so many countries across the world really gives us some protections. As one region may slow for whatever reason, wave seven in Japan, tough comp is another one, we've got other fuel that can help propel the overall business performance.

Adam Maeder

That's really helpful color. Thank you for that. And then for the follow up maybe for Bernard, on PASCAL launch in the United States. Just any metrics that you can share today in terms of where we are with procedures, or accounts, and kind of how you expect that to evolve over time? And if I heard correctly, did you say a Salesforce of 20 for TMTT? And how do you expect that to grow kind of over the next 12 months? Thank you.

Bernard Zovighian

Yes. So let me try to--first, start with the team. So we started about a year ago with a small team of people. They are all trained, certified. They are ready to go. During 2022 we have hired many people. They are in training right now. So by early '23, we will have an expanded team ready to tackle most sites in the U.S.

In terms of where are we, we focus initially on the Class 2D and Class 2F centers. The one (INAUDIBLE) device already, nevertheless, they go to training again, just to make sure we are going to have an excellent patient outcome. We are active in few centers. We have done a few cases with great outcome. And we are probably discussing right now is 40, 50, 60 centers. We are talking about contracting, all of that. Think about it though, when you (INAUDIBLE) a second with a premium price, (INAUDIBLE) like Larry said, (INAUDIBLE) conversation a little bit more slow and we need to show a benefit, innovation differentiation, what we bring from an evidence standpoint, what our team are bringing to the physicians. So there's communication happening, it's positive.

Michael Mussallem

Is it fair to say, probably not really a step function in the U.S., but probably think of more of a ramp?

Bernard Zovighian

Yeah, exactly.

Adam Maeder

Thank you.

Mark Wilterding

Matt Miksic.

Matt Miksic

Great. Thanks so much. Matt Miksic from Barclays. Mike, we're going miss you, obviously, Bernard, congratulations, and on all the progress in TMTT, and I guess Larry for having the best job of the group. So I wanted to follow up on a couple things that we've talked about. Mike, you mentioned just now that OUS maybe is going to be a stronger contributor to growth, given the penetration rates and opportunities there, product cycles you just talked about. So can you hit that middle point of your TAVR guidance, call it 10%, 10.5% if U.S. doesn't return to double-digit growth during the year? And I have one follow up.

Michael Mussallem

No, I think we need the U.S. to grow. There's no doubt about it. It's the biggest part of our business, and so we need them all to grow. So underperformance of the U.S. is not going to get swamped by over performance OUS. We really need that to come together. Now, of course, on the margin, of course, there could be some compensating, but overall, no, we need it all to work. Yeah.

Matt Miksic

Okay. That's great. And then Scott, following up on margins, so flat '22 to '23 roughly on the operating margin. One thing that many of the other companies talk about that you don't talk as much about is sort of inflationary pressures as it pertains to this next coming year. You had a big impact from FX hedges and so on. But labor is obviously a bigger part of gross--of cogs maybe for you than some of the other folks that we cover. But can you talk a little bit about if that's a part or why you don't talk so much about it as you move into '23?

Scott Ullem

Yeah. Sure. So first, just clarification on margin, absent FX margins at the operating level will be close to the same, same with 2022. But we're going to see a several hundred basis point decline based on current rates from our forecast for 2022, all due to FX. Longer term, your second part of your question was about--

Michael Mussallem

--inflation--

Scott Ullem

--inflation. Longer term, we think we're gonna see more evidence of wage inflation. Short-term, we're seeing probably a half a point to gross profit margin. So half a percentage point hit as a result of inflation. The reason we probably don't talk about it as much as some other companies is because it may not be affecting us as much. We do buy materials and supplies, but it's not as

big a component of your overall cost of sales. And so it's an issue. We've got dozens of people managing it actively, but it's not something that's really changing our overall economic outlook.

Michael Mussallem

And it's fair to say, probably some of the efficiencies that we had in supply chain end up covering up some of those inflationary matters as well. Right? Yeah.

Mark Wilterding

Anthony.

Anthony Petrone

Thanks. Anthony Petrone. Congratulations, Mike, great career building the company. Congratulations, Bernard, John, everyone on the new roles. Just want to jump back to TAVR pricing in 2023. It looks like just on the base price, that's about a 4% to 5% increase. I think we typically use a \$32,000 base price. So is that accurate? And then I think the data out there suggests that the competitors out there would have slightly lower price. And so when you think of hospitals being a little bit price sensitive, how much risk is built into that assumption? And then I'll have one follow up.

Scott Ullem

Sure. Well, yeah. We take the list price of \$1,500. So you go from \$32,500 to \$34,000. But then everybody has volume rebates in place and so those will continue. So for modeling purposes, the number is obviously lower than that. But we're not obsoleting SAPIEN 3 Ultra. So if a hospital doesn't want to move to the resilia platform, they don't want to pay the premium, they can continue on the platform they're on of SAPIEN 3 Ultra. So we're not--unlike other launchers, where we just took everybody, we knew when we did the price increase, we were gonna have to stay with the dual portfolio platform. So everybody may not come, but the people that do come can do it at a premium.

And we've also had some hospitals that says, hey, maybe we're going to use both platforms and figure out how we do it. But for me, I think it's a heart valve, and do you really want to say, I don't know if I want to give \$1,500 for the better valve? I mean, I think at the end of the day, people are going to value the innovation. And frankly, Daveen's gone from much larger price increases on a percentage basis on INSPIRIS, and it's the number one implanted surgical heart valve in the world. So clearly, people recognize the value of resilia.

And this is a really unique opportunity for us because we get to partner and draft off of everything that he's built in the last six, seven years of the resilia brand and all the other things. And the surgical community has already bought off on it. They're already huge supporters of it.

Daveen Chopra

Yeah. And as you see that, we're starting to show more and more of the data and I started talking a little bit about today, people really say, yeah, this may be a little bit different so maybe

it's worth paying a little bit more for. And so that premium, it's never easy, but it becomes a little bit more applicable. And to Larry's point, when you're talking about a heart valve saving someone's life, people are willing to kind of say, okay, let's have the best technology out there for that person because we really think that extra year or two years or whatever it ends up being is important to their life.

Larry Wood

But if you don't want to make the journey, you can stay on SAPIEN 3 Ultra.

Anthony Petrone

And the follow up would just be on the work through. So starting from echo, CT and then to an extent you can have an offshoot there, EKG, chest x-ray, cardiac MRI, and then catheterization, a lot can happen in there. We're seeing that now. And so when you think about at the TAVR center, what's being discussed there to maybe streamline that process a little bit? And is there anything potentially in the way of maybe guidelines you can change to say, maybe one step can be taken out of there and that streamlines the process? Thanks.

Larry Wood

We talk about a lot with the national coverage decision. And remember when you started, two surgeons had to review every patient because the indication was inoperable patients. So who can determine if a patient's operable or not? It can only be the surgeon. And the heart team has been really powerful, and half the procedures we did were trans apical procedures. And so there was almost this 50/50 involvement and so it was really a true team. If we look at how the procedures evolved, the overwhelming majority of the procedures we do now are transfemoral. And even the alternative access now isn't predominantly TA. People do subclavian, or trans carotid or other approaches.

So a lot of--and now we have low risk indications, which it doesn't take a surgeon to say whether somebody's low risk or not. But a lot of these things are just holdovers because they've been written in the NCD for a long period of time. So I think there's certainly things we could do to make it more efficient for patients. I think one of the things we're trying to do with the variable sizing aspect of X4 is maybe we can reduce some of the precision required about some of the pre-patient screening.

Clearly, when we take profile down, you don't have to be as precise with the access screening. We've taken transesophageal echo out of the procedure, largely, which also can take general anesthesia out of the procedure, and just to use conscious sedation. And that's one of the ways we've driven the length of stay down and closure devices. All of those things, they all contributed significantly.

Michael Mussallem

Yeah. And you can even add to that. In addition to those kinds of fundamental changes that Larry's team is trying to drive, just what he talked about in terms of educating the calve clinic

coordinators, I mean, their job is to move people through that system. And we see experienced valve clinic coordinators that have well-oiled machines. They're able to move people through the system very efficiently. And so when we put on these programs, and we allow people to share best practices with each other, they're sponges, right, and they come right up the curve.

And then the same potential exists with the target as an initiative by the American Heart Association. They're actually going out there working directly with hospitals, and developing measurements to say, okay, how well are you performing? And those kinds of things will ultimately make a difference. Yeah.

Larry Wood

And it's not that there's not a capability to do it. We have--one of our centers, a few weeks ago, they had a patient show up in the morning and they were kind of urgent. They did the entire workup and did the procedure that day. So it can be done. It just requires a lot of planning and a lot of handoffs and being done really precisely. And frankly, it's just not the way the healthcare system is built now. It's not the way they get paid. So people schedule their different office visits and do their things, but the opportunity is there to improve the efficiencies in the system more broadly.

Mark Wilterding

Rich.

Rich Neuter

Hi. Thank you. Rich Neuter from a Truist Securities. So, first question, I think one of the things people are trying to get a better sense of with the resilia pricing is, with respect to the 9% to 12% underlying growth rate, just how significant of a contribution factor is that pricing aspect? Are we talking hundreds of basis points? Is it minimal? Can you give us any sense? We're all trying to figure out what the underlying kind of growth trajectory is for the business.

Scott Ullem

It's in our guidance, but it's a small part compared to the overall unit growth that we have to get. And so it certainly is a contributor to what we have planned, but it's not the lion's share of where our focus is. And remember, like I said, we're going to be rolling out through the course of the year. It's not something that is going to be fully rolled out at the end of Q1. We anticipate that we'll be rolling it out all the way through the year next year. So we're really focused on getting patients off the sideline and seeing the unit growth. That's our primary focus.

Rich Neuter

Okay. Thanks. That's helpful. And then just, Scott, thanks for the geographic comments, I guess if I just think through it, so really, U.S. is going to be more of a back half acceleration? OUS is tough comps in the first half. So if I think of kind of the trajectory, is it fair to think or from a guidance standpoint, as we build our models for the quarterly cadence, is it realistic to say that

the double-digit potential was in the back half, really not in the first half and we shouldn't really expect double digits until the back half?

Scott Ullem

That's a fair modeling assumption for now. Yeah. I mean, obviously, we're trying to crystal ball this. We're just going into the holiday season, trying to forecast what happens as we get into Q1, with the tough comps from Q1 in 2022. So yeah, from a modeling perspective, that's a fair assumption, lower in the first half, growing year-over-year growth rates as you get further into the year.

Rich Neuter

Okay. Thank you.

Mark Wilterding

Bill.

Bill Plovanic

Great. Thanks. Bill Plovanic, Canaccord. For Larry, just a follow up on the resilia with SAPIEN 3. What percentage of the market or percentage of valves do you think in the U.S. will eventually be resilia? It sounds like you expect that transition to be complete as you're exiting '23 but is it 50% ultimate penetration?

Larry Wood

I think it's going to be the predominant valve. I don't think--

Michael Mussallem

--you know what might be interesting, is Daveen, why don't you comment on where do we stand right now in terms of resilia penetration on surgical heart valves? Because I think as Larry correctly noted, the premium was much higher.

Daveen Chopra

Yeah. As Larry said, we had a much higher percentage premium and a higher dollar value premium actually than that. And we took it--when we launched the product, actually, in 2017, early 2018, we didn't have all the data we had today. But over the years, we just had a great linear growth, where today, the vast majority of our product, the majority of the product in the U.S. is the resilia tissue. So it does actually just grow when people take it on time. And it did take a little bit for, hey, when you see a contract for the first time, and then you have a contractor, and they look at it and say whoa, wait. That's quite a premium. That's a lot higher than my competitors. It takes a little time to show the value and explain the features and show the data. But then even coming online, so it is a little bit of a process. But Larry--

Larry Wood

Yeah. I think it's going to be the primary valve. I think it will become the leading valve in our portfolio in the U.S. So I think that's going to happen, but again, it's going to take time. The other thing, too, I will say is the approval came earlier than we had anticipated. And so we're still scaling up our supply and our manufacturing and some of those other things. So that's something that paces our launch a little bit as well.

Bill Plovanic

It's fair to think that that transition will be complete as we're exiting '23 or is it something that'll--

Larry Wood

Well, I mean, I look at you launched in 2017 and there's still sites you're converting. So I think we'll get the bulk of it probably converted by the end of next year. But then I think we'll have a trickling effect that could go on for a couple years. And there may be some people that never make the journey. So I can't tell you exactly what it is, but I have both platforms available. And so it's not like that's the only platform where I take everybody there and if you don't want to make the journey than you got than you--

Michael Mussallem

--but one of the things nice is it's the same platform that we use in surgical valves. And at the same time that's going on, and it's being launched in TAVR, we've got a lot of follow up in patients with resilia. And so we're going to be able to probably speak to, what, are we going to see seven year data?

Larry Wood

Yeah. And that's what I was talking about earlier. I think when we have the seven year data, I hope that helps the TAVR business a lot when people can say, wow, we have seven years of resilia in TAVR.

Michael Mussallem

Which may not mean much to you all, but if you're in the valve business, we've seen other valves that sort of start topping off around seven years. So it's a pretty meaningful data point. Yeah.

Larry Wood

Yes. I think we see with a lot of valves, as I mentioned a little bit, each year, after kind of five years, you start to really see that deterioration occur. And with our benchtop testing so far, we think it's meaningfully different at seven years. And so then I think if the clinical data helps support that, we will feel really good saying, wow, this tissue at seven years may be better than previous generations, which I think will help Larry--Harry's group a lot and help the TAVR business a lot as well.

Bill Plovanic

And then my follow up is just, are you seeing in terms of staffing issues, procedure volumes, a difference in the benchmark sites that you have versus other sites? And if you kind of use that as your measuring stick, how do we think about that, and kind of how--

Scott Ullem

Yeah. The benchmark program for people who embrace it, and really adopt it and take on the whole program, they go from to being able to do two cases a day in their system to being able to do five cases a day. And that just makes a huge difference in terms of their capacity, because it's a lot easier to do more cases in one day than it is to add necessarily a second day. So getting the capacity, and it's also easier on us to send our people there and do the five cases rather than do two.

So it helps the whole system and it's just a much more efficient way to do it. But what we're really doing is just pulling unnecessary things out that aren't needed anymore. And a lot of these things are holdover from the early days. But when something's working, people are reluctant to change it. And they're like, sure we have the full scrub nurses here from the surgical center, but they've never hurt anybody so why not just keep them here just in case something happens. And it's just not a very efficient way to run a system. And that's why it's so important we do it in a peer-to-peer basis where it's other physicians saying, I've implemented it, here's how we did it, get administration involved, but it's not a light switch, you have to walk everybody through the journey.

Katie Szyman

But that's one area where we partner too, because if you can get to minimally invasive or noninvasive anesthesia, you can turn the room so much quicker.

Mark Wilterding

Cecilia and Matt, I see you over there. My eyes aren't as good as they used to be. I'm sorry it's taking me so long to get that far away, but maybe the two of you, and then we'll wrap it up with one other after that.

Cecilia Furlong

Cecilia Furlong, Morgan Stanley. Thank you again for hosting this. I wanted to ask, just, Larry, your comments around where you are today, 850 or so centers in the U.S. and the thought of expanding TAVR teams going forward. And can you just speak to capacity in the system if you had full staffing today versus how you think about just the growth and need to continue to expand TAVR team capacity?

Larry Wood

Yeah. I think we'll continue to add centers, but it's not going to be at the same rate we have historically. So as new centers want to get added, I'm sure we'll see, I don't know, make up a number, 10 or 15 a year, maybe that might come on. So the overwhelming majority of our

growth is going to come from existing centers rather than adding new centers. But centers are showing the capabilities of being able to add capacity throughout this entire journey.

If you look at some of our volume we were doing even a few years ago, we were doing it in 400 centers. So we have a lot more centers now than we ever used to have, and they've shown the ability to add that capacity. And benchmark isn't fully deployed. We have a lot of hospitals have added a second day or in some cases, they've added a second team. So the capacities there, I think it's just a matter of connecting all the dots for them. It's getting the patient referrals flowing, making sure they understand the need for adding an additional day or adding an additional team and just working through that process. But I don't have any question the capacity is there in the system to handle more patients.

Cecilia Furlong

Okay. And just wanted to follow up on the patient side. You talked about initially last year, direct patient outreach. You talked about it today, again. How much of an impact do you think that's having, investment that you're anticipating going forward? And then just would love your comments, I mean, too just the the discussion around the risk that physicians are having with patients, how that's evolved from when low risk was approved in 2019 and in the benefits, drawbacks of TAVR versus surgical? And thank you.

Larry Wood

That's the best one question I've ever gotten. In terms of our outreach efforts, there's a lot of outreach efforts where we do--that we can connect and say, we reached out to these patients, and we reached out to these referrers, and we saw a pickup in referrals from that general cardiologist. So we know that that program is working. When you do things like television, or you do things like some of our digital media, it's harder to say. People anecdotally say, yeah, I saw the TV commercial, or they'll anecdotally say, I saw this on social media.

Once they connect up through our digital platforms, though, through like find a TAVR, and they give us their email address and want to be caught up, then we can find them in the system, and we can find later if they were actually treated. And we do see a lift from our therapy development effort. So we think they are working. It's just probably the hardest time right now to run analytics, because the last two years have been so choppy with COVID, and variants and all those sorts of things. And so you don't really have that steady state. And remember, it takes patients, on average, four to six months to move through the system, and it can be longer for the older patients.

So the work that we're doing today to energize somebody, those patients may not show up for several months into the system. And so we got to factor that all into our analytics. But we're committed to the outreach programs that we're doing. We know they give us some lift, but it's not super easy to necessarily quantify exactly which program has the greatest lift. But we're continuing to run the analytics and we're always fine tuning our investments for the things that--we get early reads that say this is working better than something else.

In terms of the physician discussion with the patients, it certainly has evolved over time, but it lags. When we go out and do survey work, even for general cardiologists, there's a shockingly high percentage that don't even realize TAVR's approved for low risk yet, even though that approval came some time ago. And so once we find that information out, we can fine tune our education. But you still have surgeons when they talk to patients and they say, you're a perfectly good surgical candidate. It's a tried and true. We've done this. And so there's still some of that that goes on.

But that to me is still less of the issue. The issue that I'm more passionate about, if somebody comes through the system and they're low risk, and they end up getting the surgery instead of getting TAVR, so be it. That's not really--I don't care that much about it. The fact that in an elite institution, 50% of the people with a guideline indication for AVR are not moving through the system. And that's just where there's just all this gold buried there, and we have to figure out how to address it. And that's why it's become a huge area of focus for us.

Daveen Chopra

Yeah, because the TAVR, SAVR thing is now the minority. That's like the edges, right? If you look at surgical patients, the majority in the U.S. are aortic regurgitation, or concomitant cases, or something else that's on label that's indicated for surgery, but probably doesn't make sense. That doesn't make sense for TAVR. And if we just get more of those 50% higher, that's really what's going to drive the system, versus a we get a little bit of TAVR, SAVR ratio shifting. I think that's the minority of the growth.

Larry Wood

We've had--I mean, again, it's been a little choppy the last couple years, but we've had a number of times when we get a new indication, we see TAVR spike, but surgery grows faster than what had been growing before, because patients come off the sideline, and not every patient's a TAVR candidate and we see surgery grow. So it is really about getting those patients energized and getting them off the sideline. And some of that's getting the GCs energized. Some of it's getting the patients themselves or their caregivers energized.

Matt Taylor

Matt Taylor from Jefferies. So two questions to add to these core debates, please. So one is, I was hoping you could address the idea that some investors have brought up that excess mortality in the eligible TAVR, SAVR population has led to this kind of air pocket because of COVID over the past few years. Do you have any data or thoughts you could share on that as to whether that's a big enough factor to have changed your growth rates?

Larry Wood

So the excess mortality, we do know that elderly patients were disproportionately affected by COVID. And so when you look at the people that died over the age of 80, I think it was around 150,000 people or something like that that had died that were over 80. And so if you look at

prevalence rates of TAVR, you'd probably say, 5% of them could have been potential aortic stenosis patients. And so you can do the math on that. And certainly, there's some patients lost there, but that was sort of a one year phenomenon.

And even when you do that math, and you compare 10,000 people or 15,000 people, if that's in the in the loop, compared to the treatment rates, and the overall group of people that's sitting out there, it's a really small number in the big scheme of the under treatment. And so there certainly were some patients lost, but I don't think that was a big headwind to what we saw.

Matt Taylor

Great. Thanks. And then one follow up. I like your slide on the VCCs, and I guess there's some good news and bad news there. You're trading a lot, but a lot of churn. So my big picture question is, in the current environment, there's all these staffing issues that are bottlenecks. How much of it is just macro and how much of it can you actually influence and control? If you could give us two decimal places that would be great.

Larry Wood

18%, I don't know. Every hospital we talk to complaints about staffing. There's not a hospital that we talk to that doesn't say, we can't hire enough nurses, or we can't get enough staff here. And it's not just nurses and hospital staff. It's sometimes the people that help turn over the room and axillary staff and those sorts of things. So that's clearly a problem. But we also--we have a number of hospitals that are sort of back at their pre-COVID capacity. And those hospitals complain just as much about staffing as the hospitals that aren't at their--that are growing at the same rate.

So I think staffing is a headwind, but I think hospitals are overcoming and they're figuring out a way to get their patients treated. And the thing that Mike said, is absolutely true. Hospitals are hurting right now, economically, some of the costs, some of the other structures. They're not going to get a radical margin improvement. The only way out of it for them is growing procedures. And you look at the cardiac procedures that are pretty profitable for hospitals, and TAVR procedures at most hospitals are pretty profitable procedure. So their way out of their economic challenge is to get their procedure volumes back up and to grow again.

Katie Szyman

That's true.

Matt Taylor

Thank you.

Mark Wilterding

Okay. We have time for one more question, and then I'll turn it back over to Mike who's going to introduce a really special patient video. To the extent I wasn't able to get to your questions, I apologize. We're going to have a reception right after this where we'll have the management

team available for another hour. And so just before the last question, I also want to thank Kim (INAUDIBLE), Linda Wright and Oliver (INAUDIBLE), really appreciate your help making this event possible. You guys are great.

Last question to the analyst who traveled the furthest, I think, Ed (INAUDIBLE), all the way from London. And then we'll go to the patient video.

Ed

Thanks, Mark. And great to be here. But in a quick follow up on PASCAL. We've talked a lot about the U.S. opportunity, but let's look at Europe. You've got great success. You're well established now. Can you update us roughly what you think your market share now is in Europe? And related to that, also the duration as sustained effect? That's obviously important data. Have you seen already a benefit in Europe from that data with the physicians you're speaking to?

Bernard Zovighian

Thank you. So I'm sure you remember, we started in Europe in Germany. From the beginning, it is where we made a lot of investment, the team, physician training, opening account. We are very pleased about our share position in Germany. I'm not ready to give you a number, but very pleased about our share position in Germany.

PASCAL is well adopted by the largest German centers. We have great outcome. At (INAUDIBLE) to answer your second question, some of the physician multicenters were presenting PASCAL, and they were doing a (INAUDIBLE) match against mitral clip with great outcome. So what we see Europe is Germany, we have a great footprint. France, which is the second largest market in Europe, we are not yet present. We are going to use Class 2D data to get to approval and reimbursement in France. So in other country in Europe, we are expanding, and there is still work to do. We need to, in the next couple of years, we need to open up new centers across Europe, and also in Germany. So we are pleased to where we are here and more to do, basically.

Ed

Thank you. And I have a very quick follow up for Katie. To turn around the capital discussion, with what you're doing with smart recovery, frankly, you're helping hospitals save on time, reduce costs. So is that actually something that they want to cut right now?

Katie Szyman

Is it true that hospitals want to save time and reduce costs? Is that the question?

Ed

Well, they do, certainly. So I would suggest HemoSphere health is a nice solution for them.

Katie Szyman

Yeah. I mean, I think it's very much similar to what we've been talking about here today. If they can actually get patients out of the ICU faster, then they can bring in more procedures and take more risk on all of these cardiac procedures that we're talking about. And so the more that we'd use their own baseline data to show them that they can actually get patients home faster, they can actually get the throughput, then it helps everything. I mean, it helps the system, and it helps nursing, it helps everything. And so we have seen the hospitals that adopt smart recovery, getting that efficiency and that's why you see kind of this correlation to the benchmark program that Larry was talking about. Thanks for the question.

Michael Mussallem

Okay. So thanks so much for all your interest in Edwards. We never like to close one of these sessions, without reminding ourselves why we're all here. And then as we mentioned before, what we do is kind of a team sport. And of course, the company is committed, but the physicians that we serve, the regulators that we work with, the communities that we're in, and frankly, the investors in our company are all part of this, and it leads to some pretty fun stories, and we've got one to share with you now.

(VIDEO BEGINS)

Dorothy Cantor

I'm Dorothy Cantor. I'm 85 years old, although it's hard for me to believe that. I started out as a teacher, but I went back and got my doctorate when I was 40. I ran for various offices within the American Psychological Association and was the ninth woman President. That gives me great pride. Over the course of my career, I wrote or edited six books. The book of which I'm most proud is one called *Women in Power, The Secrets of Leadership*. I've always been interested in empowering women, and so mentoring has become an important part of my life, post retirement.

Nobody in my family ever died of anything but cardiovascular disease. So four years ago, I had a really weird pain in the center of my chest, and I learned I had had a severe heart attack. I spent about 17 days in Morristown Hospital. They told me that I had developed severe mitral valve regurgitation as a result of the heart attack. I was so weak at that time, that when I got to a corner, I prayed silently that there would be a red light so that I could stop and pause and breathe. I do not like being impaired and I felt impaired.

It took two years before the doctors felt that I was ready for that magical PASCAL that they had been talking about. My son was picking me up the day after I had the PASCAL and he said to Dr. Kiperman (PH), mother's coming home with me. My guest room is on the second floor. Should I trade with my mother so she doesn't have to walk up the steps? And Kiperman said to him, then why did we do the procedure? And the results were amazing.

I would say I live a better than normal life for an 85 year old woman. There is barely anything that I cannot do. Nowadays, when I get to a corner, I get pissed if there's a red light because I'm

a New Yorker, and when you get to the corner, you want to keep going. And I actually got published again. A group of colleagues and I that meets Tuesday night over cocktails, we call it drinks with shrinks, did a research project, wrote a paper and it just got published in the New Jersey Psychologist, with perhaps the oldest authorship of all time, average age 81.

Now, I travel all over the country to see my family and it's very important to me that I see them, that I be a part of their lives. All of this is possible from me because I feel well, and I feel well because I have the PASCAL. And from the bottom of my heart, I thank you.

(VIDEO ENDS)

Michael Mussallem

So pretty fun, right? AND it's really a privilege to be able to do what we do. I'm honored to say that we've got Dr. Dorothy Cantor with us here today and she's going to be willing to hang around a little bit. Thanks for being here, Dorothy. You give us inspiration. So thanks, everybody, for your interest in Edwards Lifesciences. Me and the rest of the presenters are going to be around, and Dr. Cantor.

Dorothy Cantor

(INAUDIBLE). I'm the one who proves it works. If you have any question, talk to me.

Michael Mussallem

Thank you. Thanks, all.

EXHIBIT 61

February 22 is Heart Valve Disease Awareness Day. Take control of your severe aortic stenosis, the most common type of HVD, by using this Informed Discussion Guide.

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By choosing one of the Edwards SAPIEN transcatheter heart valves, you are getting one of the most widely used TAVR valves around the world, having been implanted in over 763,000 patients around the world.*

TAVR with the SAPIEN 3, has similar durability to that of the leading surgical valves at 5 years.^{†‡1,2}

Edwards' newest valve, the SAPIEN 3 Ultra RESILIA valve is a bovine (cow) heart tissue valve that has been treated with a special Edwards technology to block calcium build-up on the valve, potentially allowing the valve to last longer.^{†1}

Both the SAPIEN 3 Ultra RESILIA valve and the leading surgical valves use RESILIA tissue, known to block calcium build-up on the tissue, which could potentially allow the valve to last longer.^{†1} Before today, the RESILIA tissue was only approved to be used on surgical heart valves.^{†1}

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- An outer sealing skirt surrounds the bottom of the valve, to help stop any possible leakage around the valve.



Important Risk Information

- SAPIEN 3 TAVR valves come in four unique sizes to provide a better fit for each individual patient.

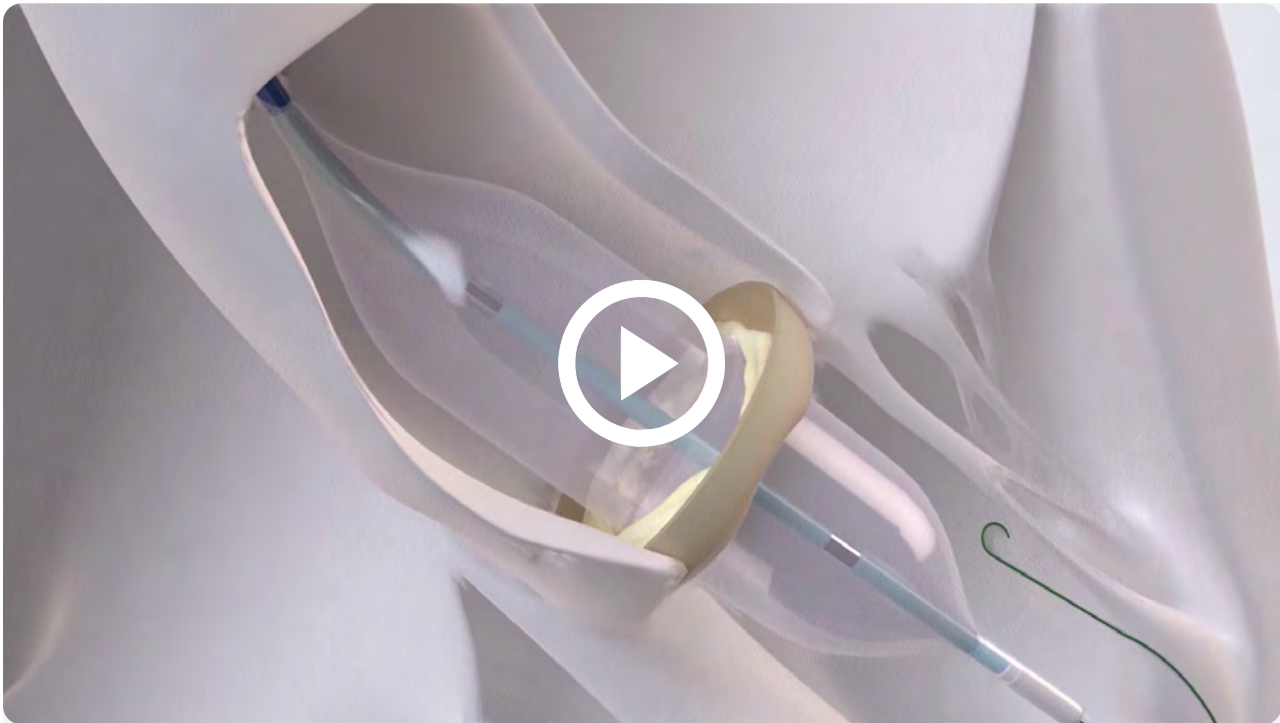


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- The SAPIEN 3 TAVR valves are designed purposely with a specific low frame height to facilitate future procedures, if needed.⁵
- The SAPIEN 3 Ultra RESILIA valve is a bovine (cow) heart tissue that has been treated with special Edwards technology to block calcium build-up on the valve, potentially allowing the valve to last longer.¹¹
- Up to 75% of patients who get TAVR also have coronary artery disease.³ By getting one of the SAPIEN 3 TAVR valves, your physician may have better access to your coronaries in the future, should you need another procedure, due to its unique shape and low frame height design.

Serious risks associated with the TAVR procedure, similar to those of open heart surgery, include death, stroke, serious damage to the arteries, or serious bleeding.

TAVR procedure animation



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Watch the TAVR Procedure Animation



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Understand why your first transcatheter valve choice matters. Know the different types of valves available to you. Don't settle for just any TAVR valve. Make sure you understand your options.

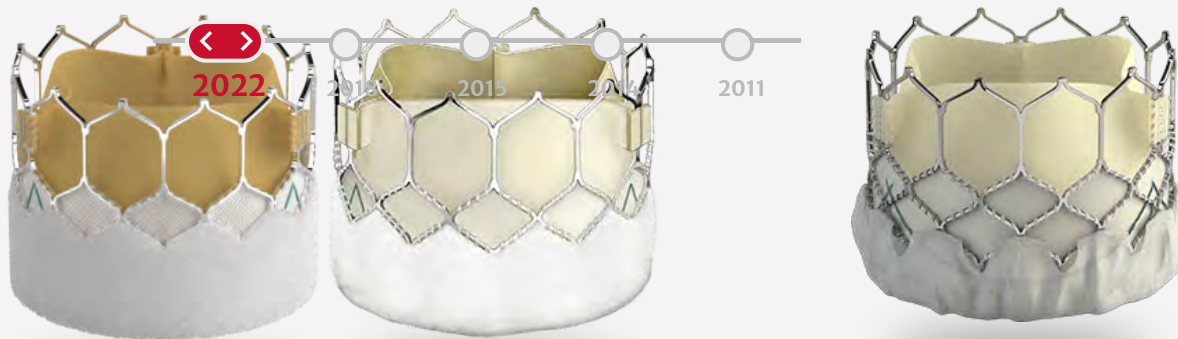
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FDA Approved 2022

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Edwards' commitment to best-in-class technology continues with the SAPIEN 3 Ultra valve. Built upon the proven SAPIEN platform, the SAPIEN 3 Ultra transcatheter heart valve was designed with patients' future needs in mind. Its low frame height and large cell design easily facilitates future coronary access if a patient requires a procedure post-TAVR. It continues to provide alternative options for patients other than open heart surgery.

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Important Risk Information

Ultra RESILIA transcatheter heart valve is made with RESILIA tissue (previously only used on Edwards surgical valves) and designed to reduce calcium build up on the valve tissue, potentially allowing the valve to last longer.*¹

Next page: know the clinical difference

Learn about the benefits of Edwards valves and what that means for getting back to the life you love.

> [Go to the Clinical Difference Page](#)

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2. Pibarot 2020 (S-13919) describes 5-yr PII S3i trial outcomes similar between S3 and SAVR, based on VARC3 definition.
3. Coronary Angiography and Percutaneous Coronary Intervention after Transcatheter Aortic Valve Replacement. JACC 2018: 1360–78.

*Currently, does not include the SAPIEN 3 Ultra RESILIA valve.

[†] RESILIA tissue has not been studied for long-term results in patients.

[‡] Propensity matched analysis of intermediate risk patients using VARC3 definitions of SVD and SVD related BVF at 5 years.

[§] Indication for aortic THV-in-THV with demonstrated future coronary access (68/68 patients).

[¶] The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and re-hospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.

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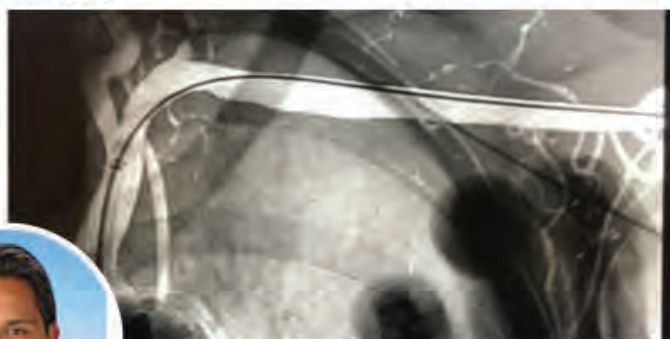
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EXHIBIT 62



Raj Tayal

2,100 Tweets



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Raj Tayal

@RajTayalMD

Interventional Cardiologist. Director, Cardiac Cath Lab and Structural Heart Disease, Valley Hospital. Clinical Asst Prof, Mount Sinai

📍 New Jersey, USA [🔗 linkedin.com/in/rajtayal](https://www.linkedin.com/in/rajtayal) 📅 Joined August 2017

1,277 Following 5,249 Followers

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Raj Tayal Retweeted



Hady Lichaa, MD, FACC, FSCAI, FSVM, ... @HadyLichaa... · Dec 11 ...
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27

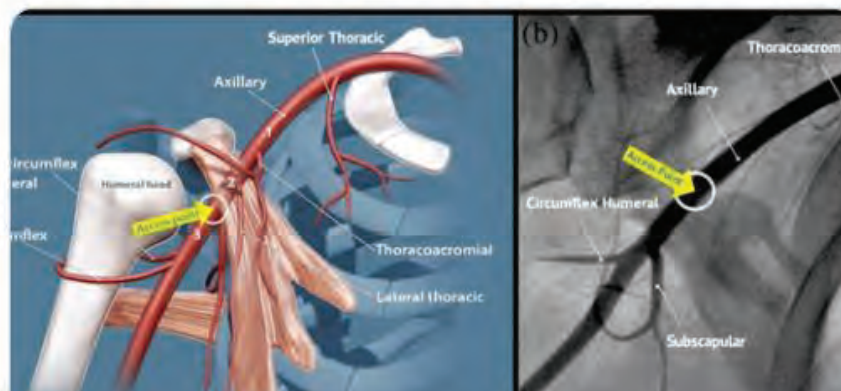


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Official feed of Edwards Lifesciences.
 Committed to addressing the unmet
 needs of patients with structural heart
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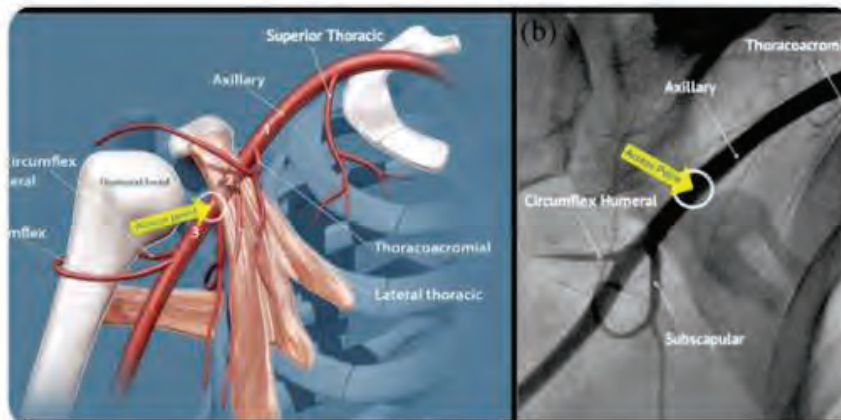
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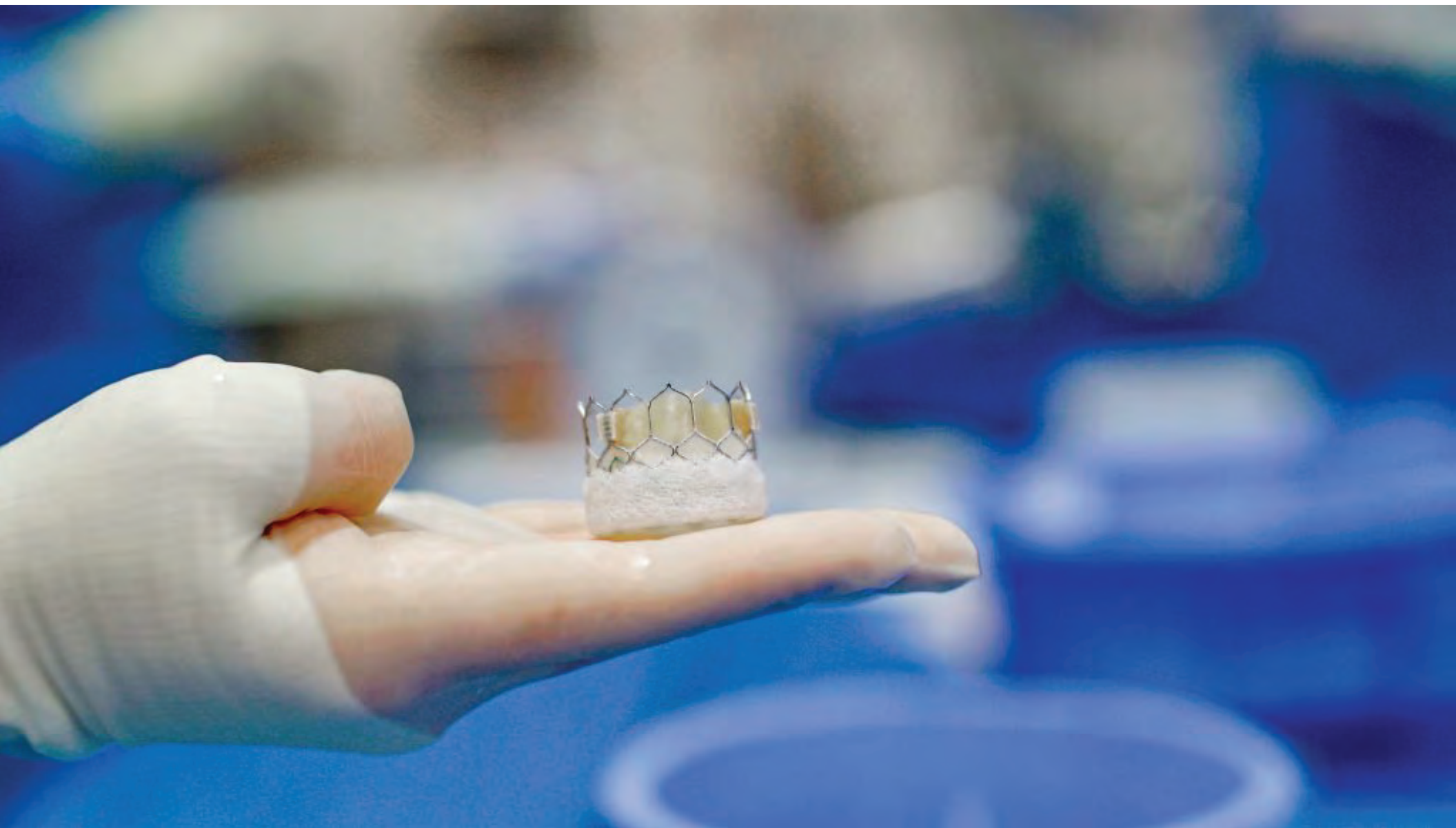
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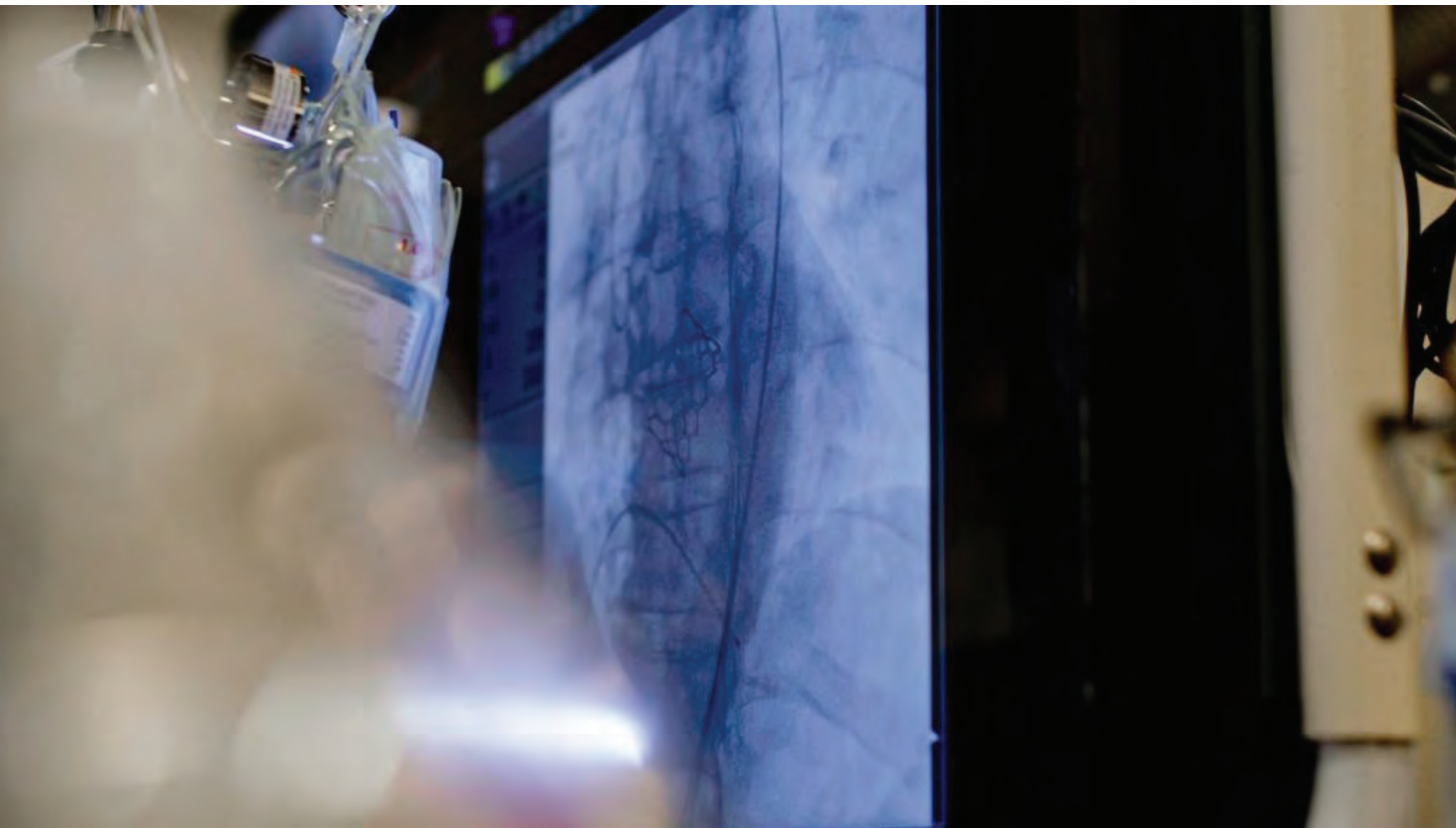


EXHIBIT 63

Transcatheter Aortic Valve Replacement

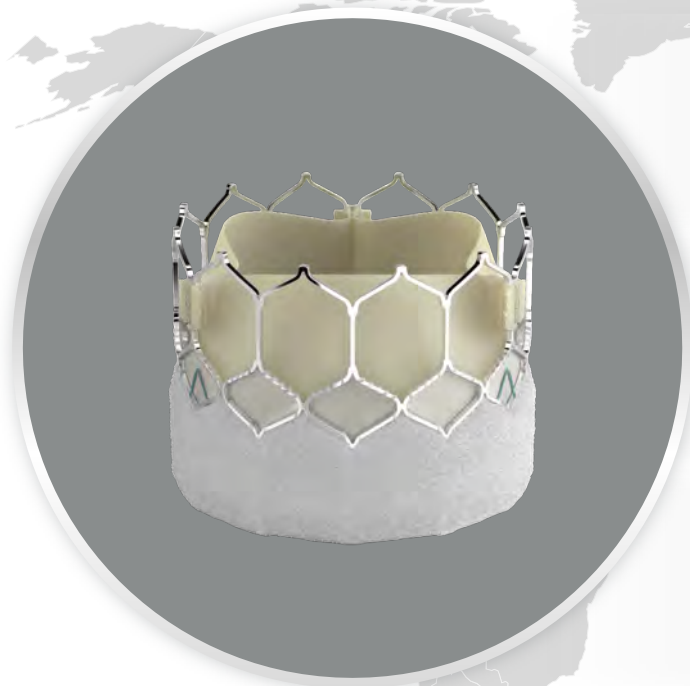
Larry L. Wood
Corporate Vice President
Transcatheter Aortic Valve Replacement



Edwards

Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

Key Pillars of Our Strategy



**Increase Therapy Adoption
in Growing AS Opportunity**

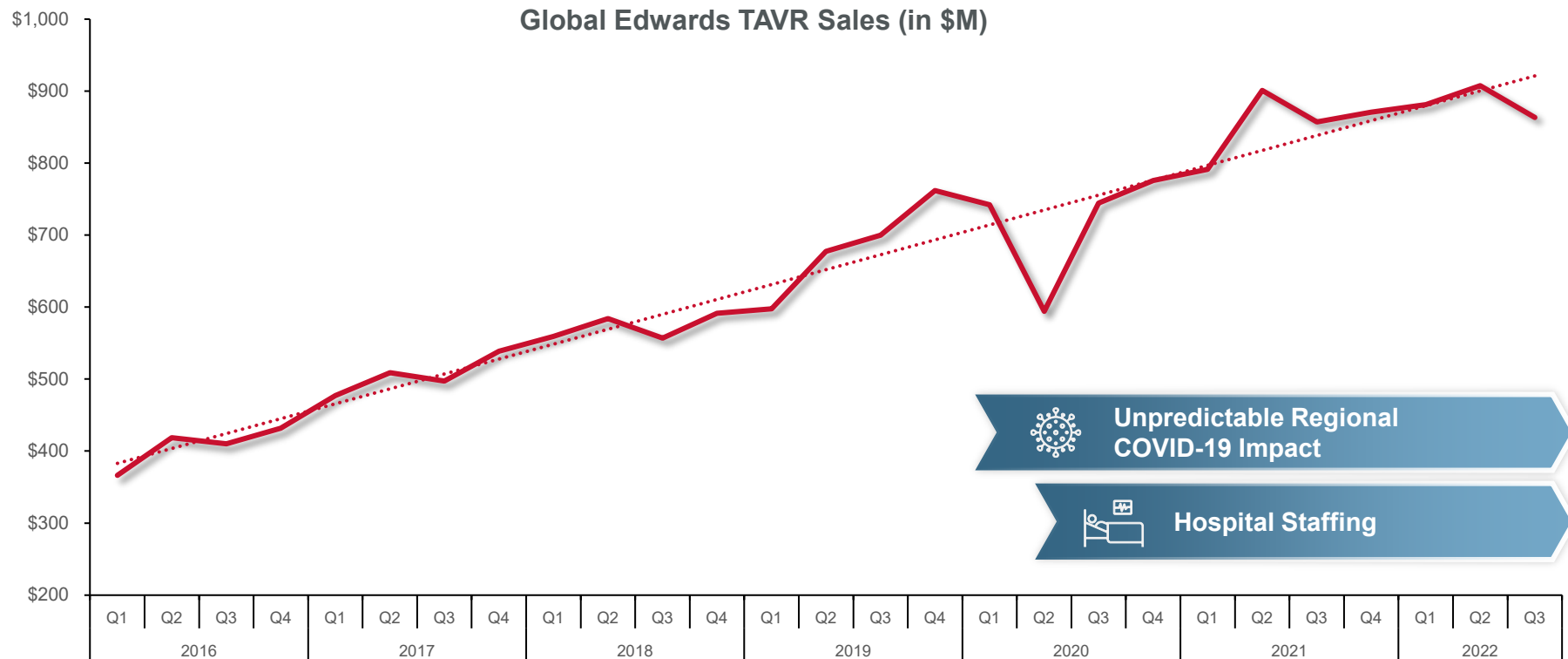


Expand Indications

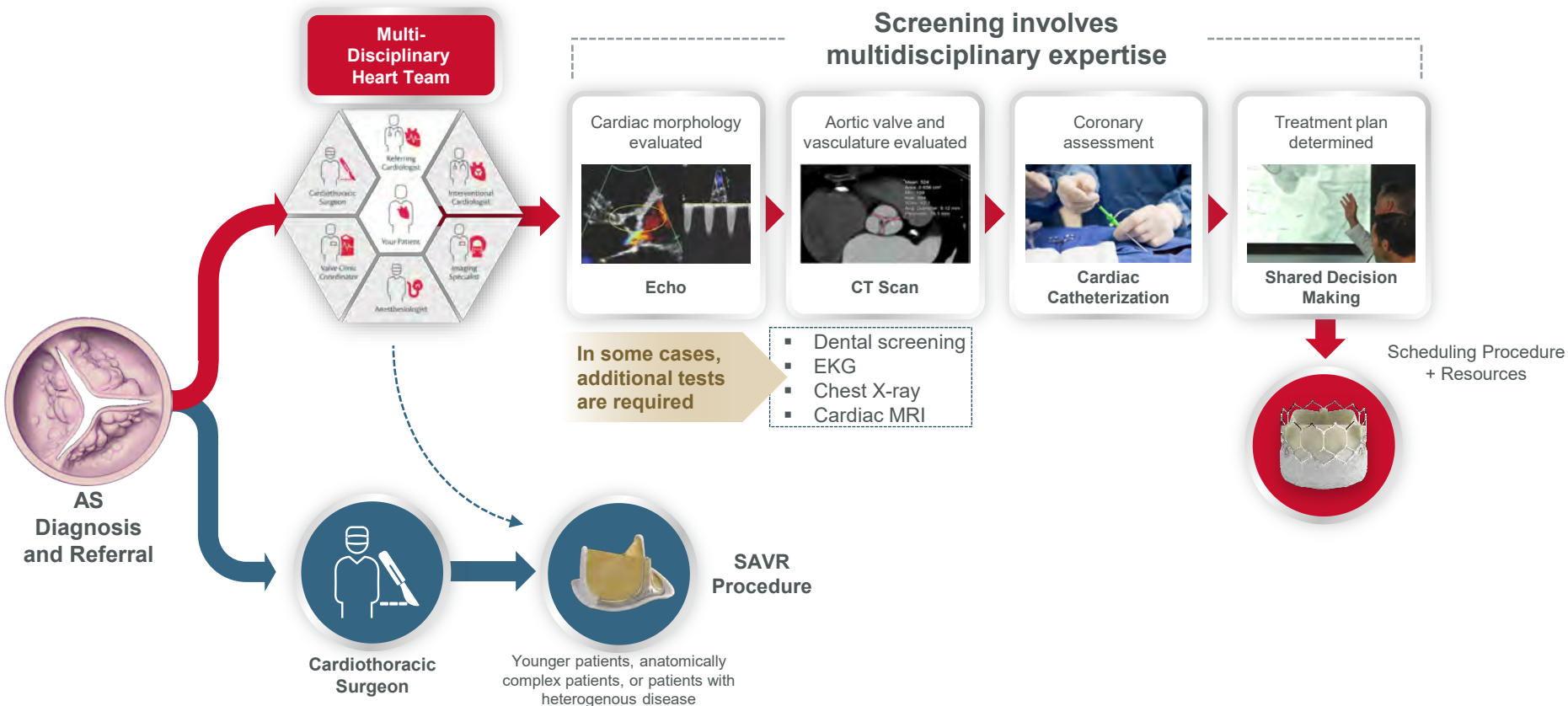


**Deliver Strong
Portfolio Innovation**

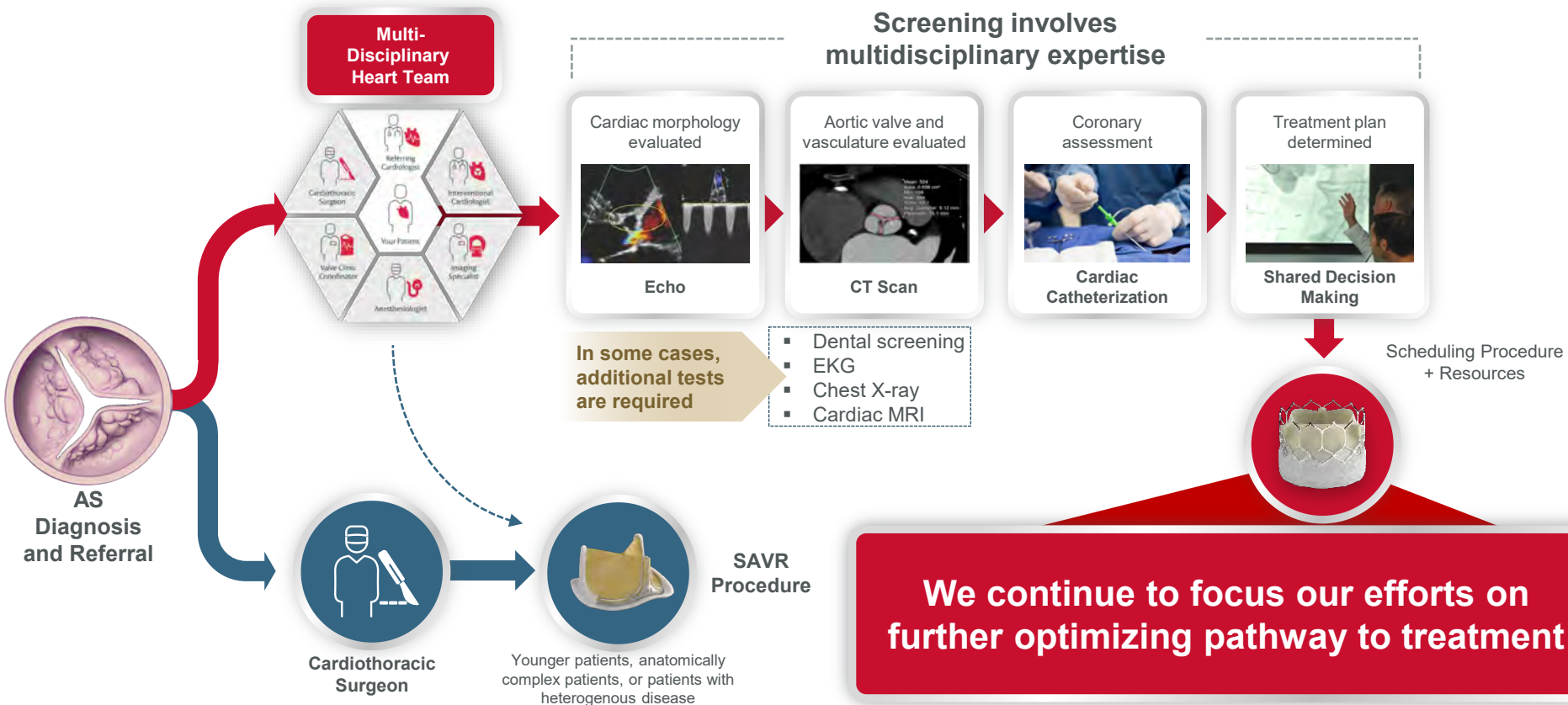
Despite challenges, global EW TAVR has delivered double-digit growth over the past six years



Administrative requirements before TAVR are higher than other service lines, and staffing shortages impact TAVR patients



Over the years, we have improved TAVR efficiencies

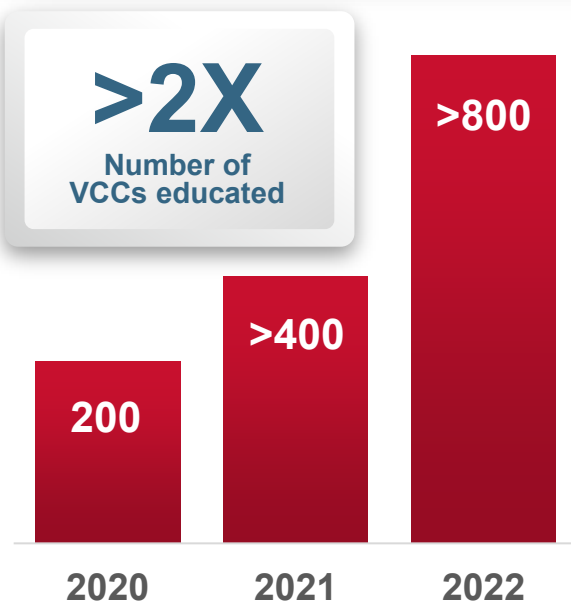




We Remain Focused on Supporting Hospitals as Trusted Partners

Valve Clinic Coordinator Education Programs

Provider Education Programs



>2X
Number of
VCCs educated

VCCs are typically trained nurses who support patients from referral through post-TAVR procedure follow-up

Edwards Facilitated Peer-to-Peer Education Programs:

- **Quickstart** – first 30-60 days foundational program
- **Level 1** – for new VCCs to support TAVR program development
- **Level 2** – for experienced VCCs to support TAVR program optimization

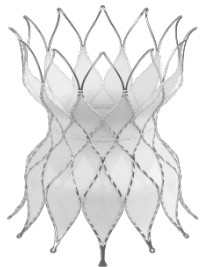


300+
fellows expected to complete programs in FY22¹

225+
HCPs²
completed programs this year



We Continue to Deliver On Our Long-Term Growth Drivers



ALTERRA

Pulmonic Adaptive
Pre-stent launched

Commercial



SAPIEN 3 Ultra RESILIA

Approved in the
U.S. and JPN



SAPIEN X4 System

ALLIANCE Trial
enrollment started

Technology



EARLY TAVR Trial

Enrollment complete;
in follow-up

Indication Expansion

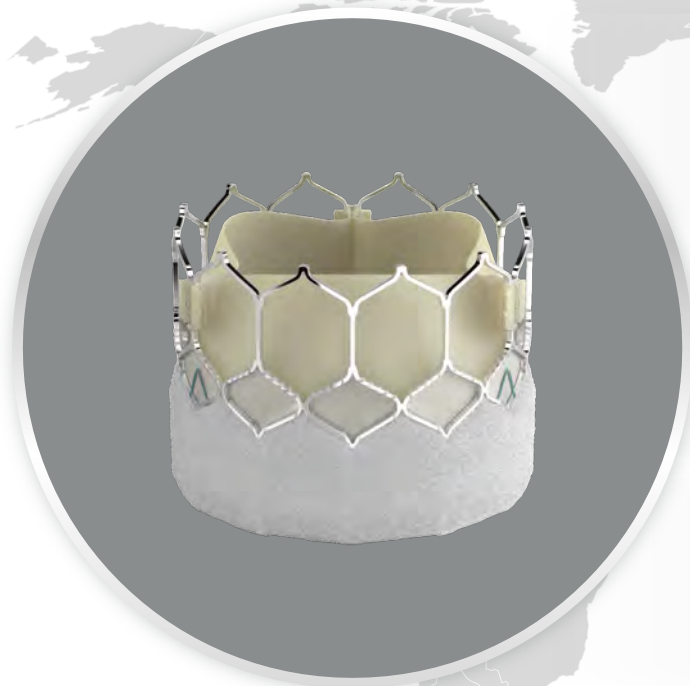


PROGRESS Trial

Enrolling for
moderate AS

Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

Key Pillars of Our Strategy



**Increase Therapy Adoption
in Growing AS Opportunity**



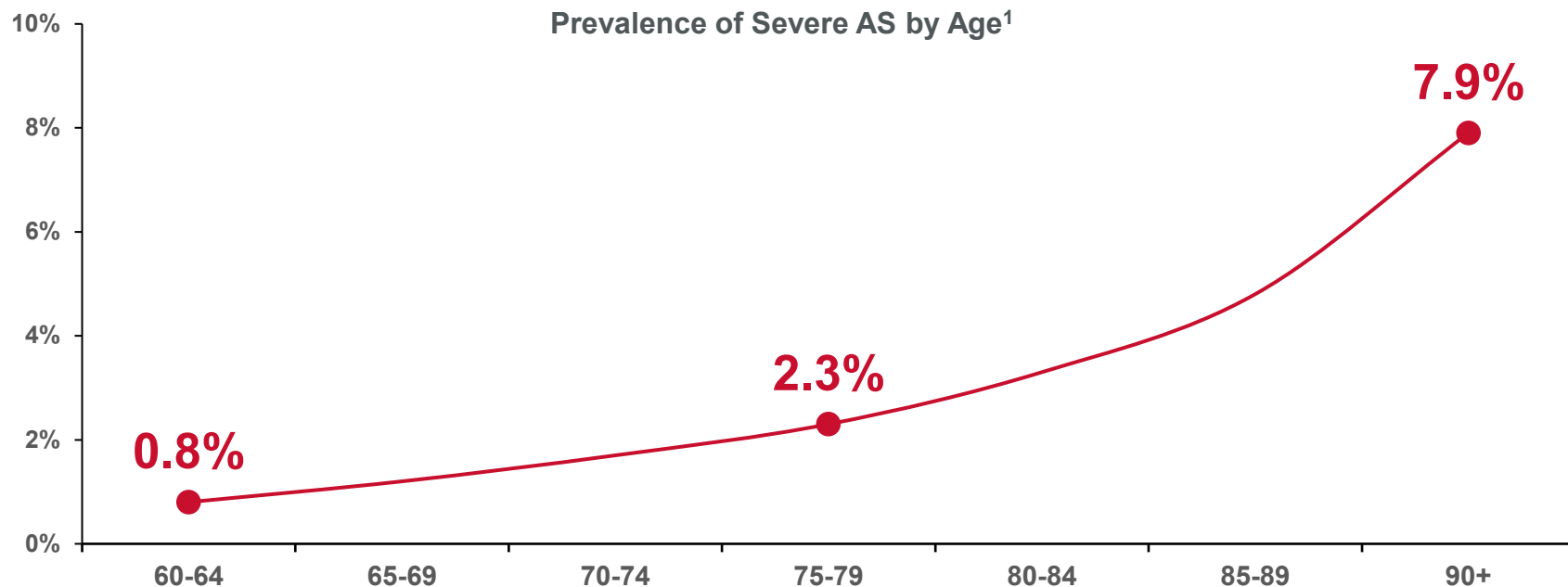
Expand Indications



**Deliver Strong
Portfolio Innovation**

Severe aortic stenosis is a disease of the elderly: Prevalence increasing with age

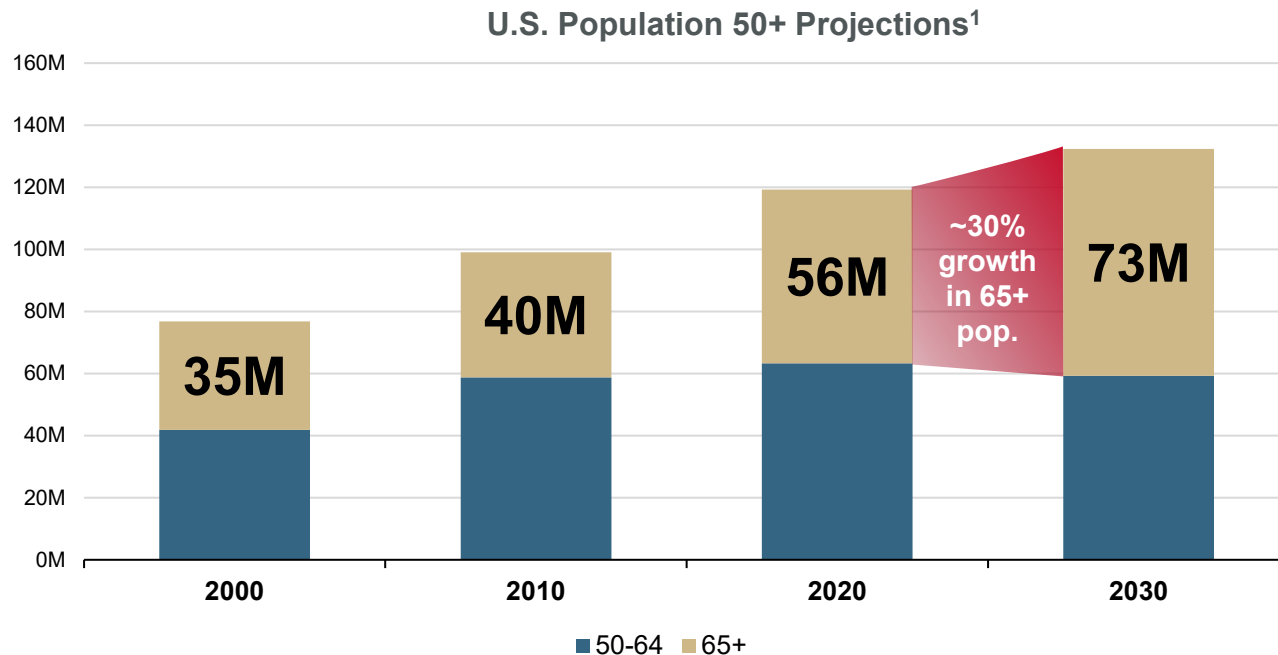
Clinical research papers reaffirm higher Severe Aortic Stenosis prevalence in the elderly





Rapidly growing aging population increases the burden of severe AS

By 2030, we expect to see significant growth in the 65+ population



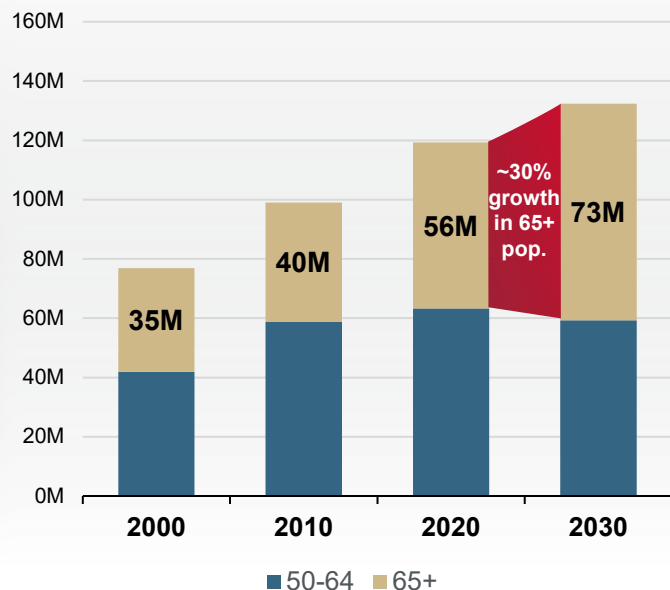
~10,000
People turn 65
years every day²

All Baby Boomers
will be 65 or
older by 2030²



While the AVR treatment growth has accelerated since the advent of TAVR, treatment utilization remains low

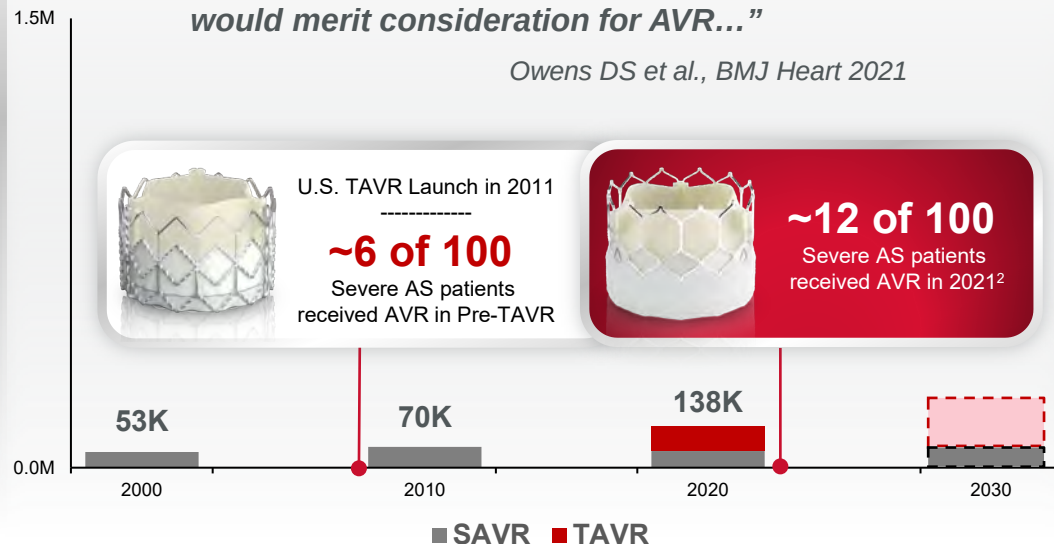
U.S. Population 50+ Projections¹



Growth in AVR Treatment²

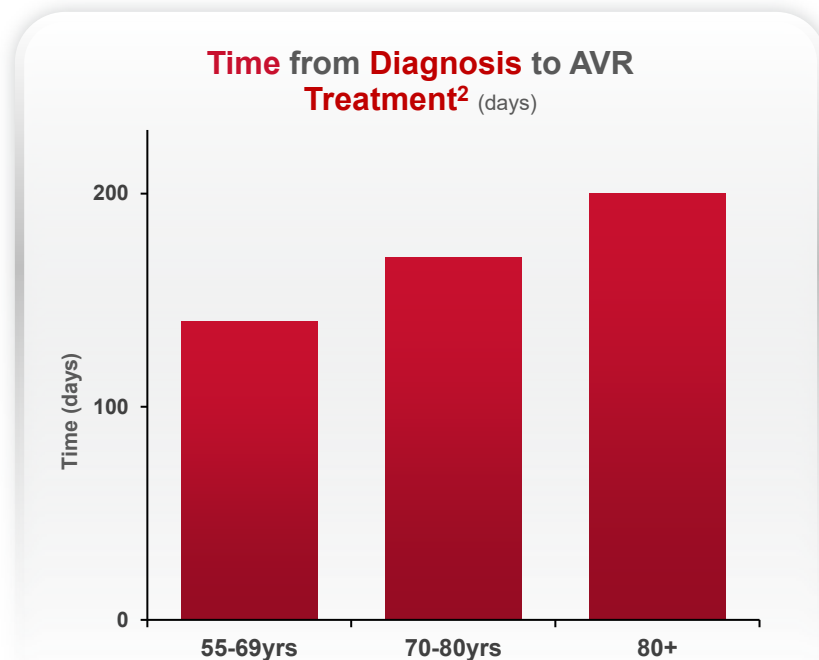
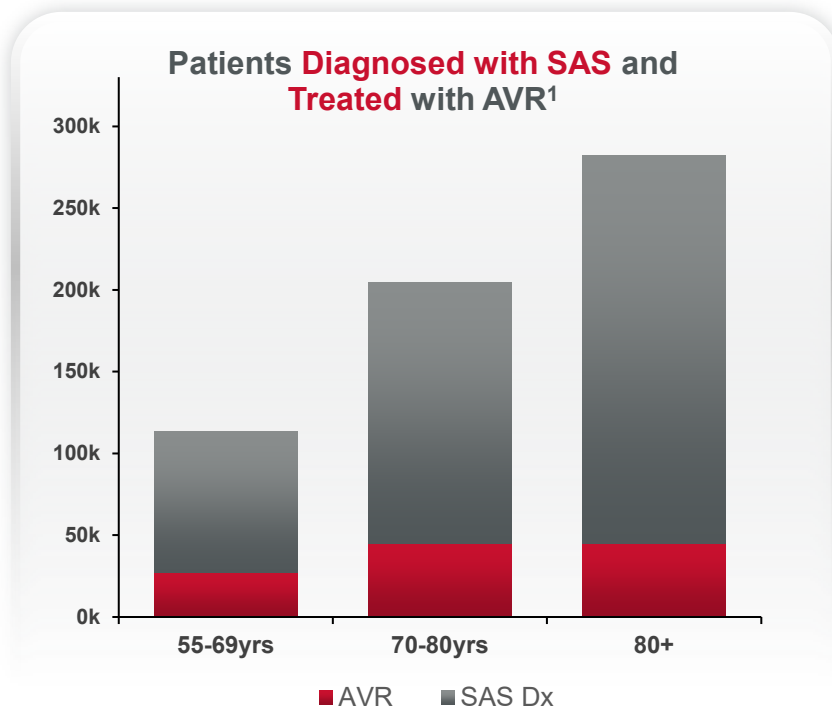
“... currently ~1.3 to 1.6 million Americans would merit consideration for AVR...”

Owens DS et al., BMJ Heart 2021

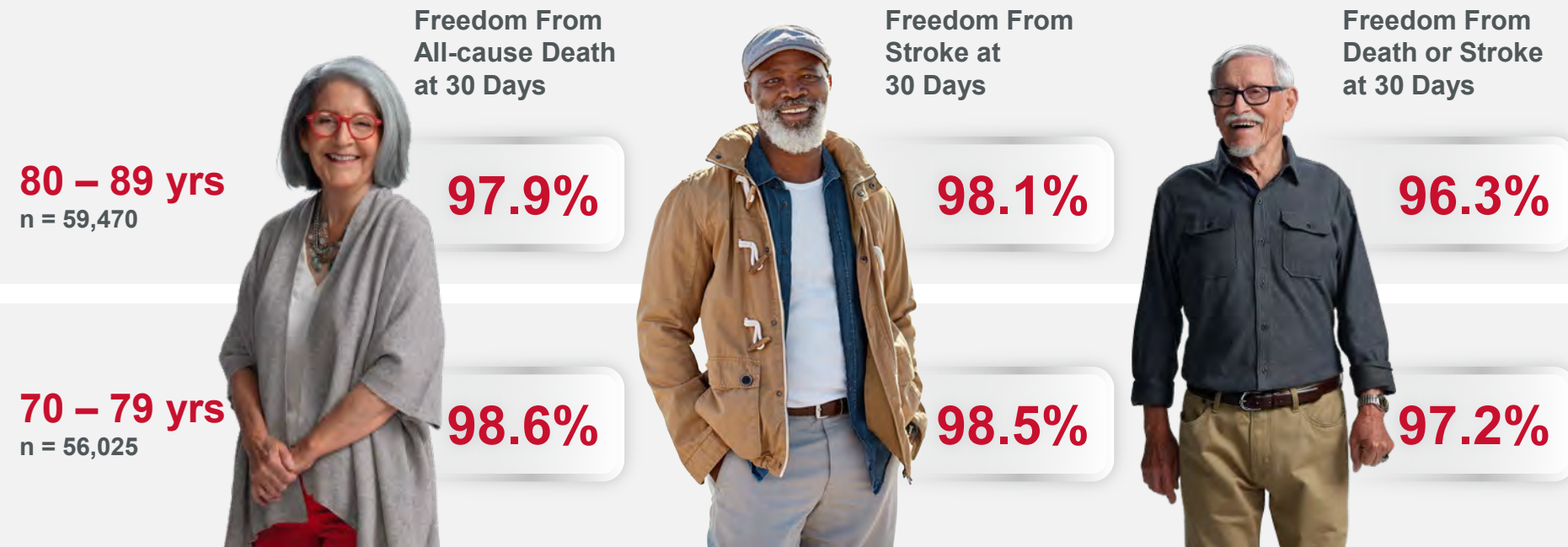


(1) U.S. Census data: 2017 National Population Projections Tables (2) EW Internal Estimates of U.S. AVR Volume. Therapy penetration of ~12% calculated based off the 1.3M Severe AS patients; Ref: Cumulative burden of clinically significant aortic stenosis in community-dwelling older adults; Owens et al. 2021

Undertreatment is exacerbated in elderly patients, who also have longer time to treatment

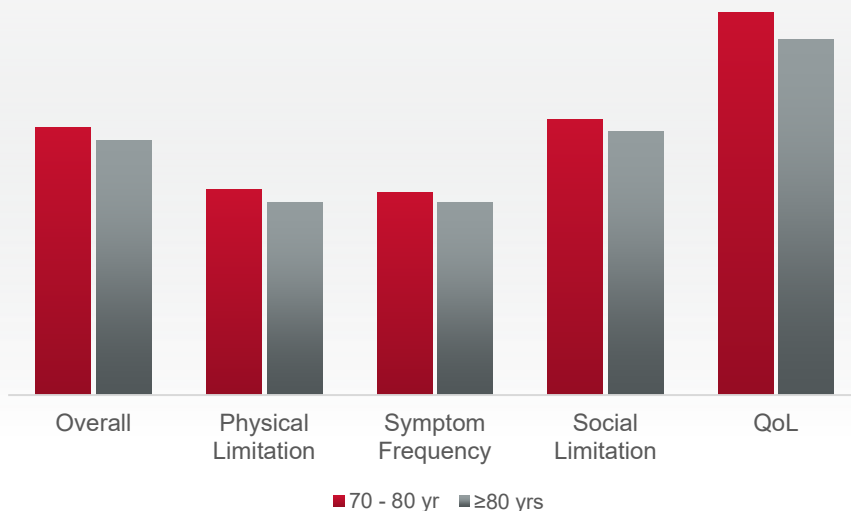


Patients in their 80s have as favorable TAVR outcomes with Edwards TAVR as patients in their 70s

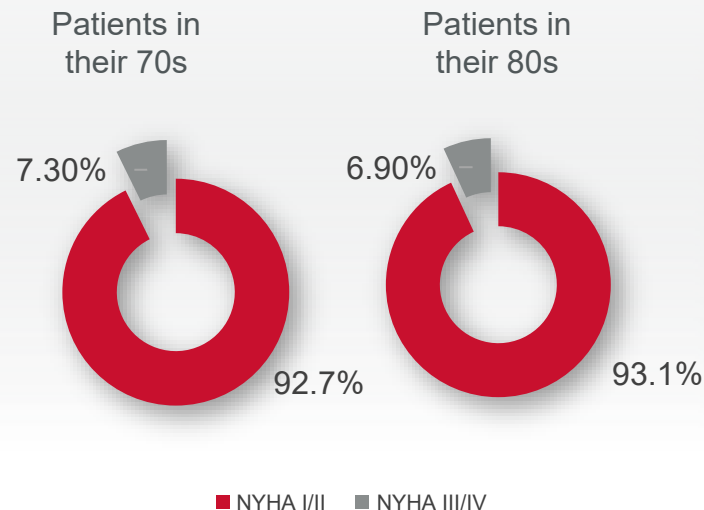


After TAVR, QoL in 80+ year old patients improves as much as QoL of patients in their 70s

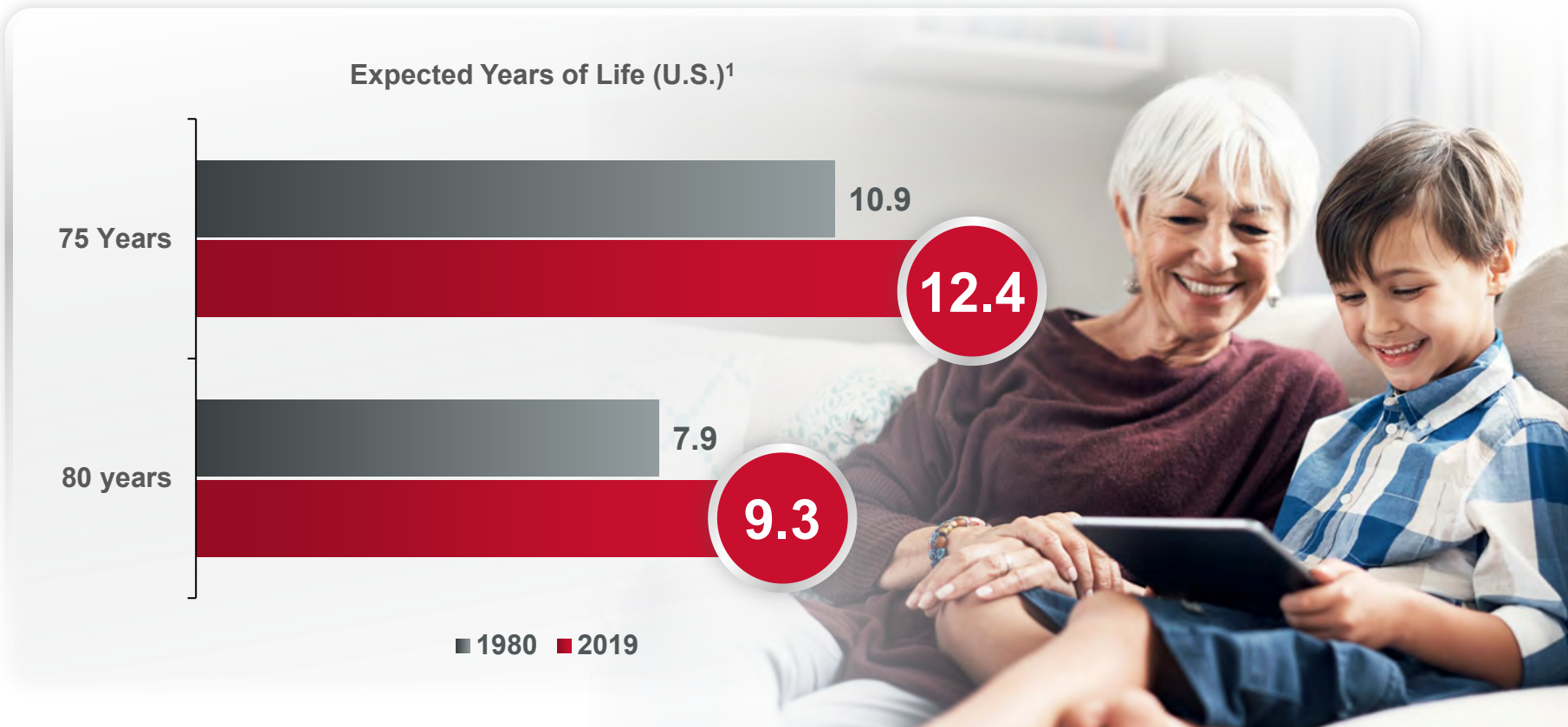
Change in KCCQ (Baseline to 1 Year)



NYHA Class at 1 Year

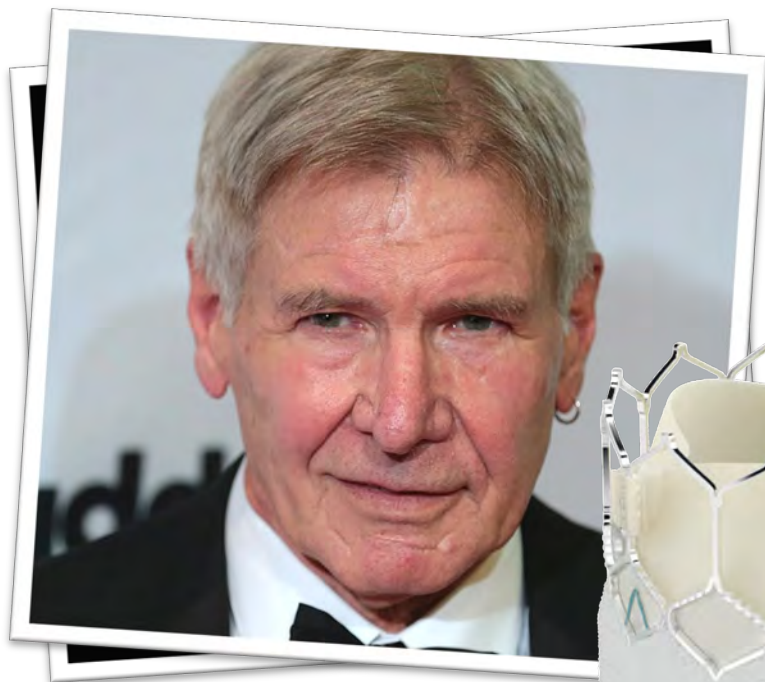


Elderly patients are living longer



(1) https://www.cdc.gov/nchs/products/life_tables.htm for 1980 and 2019 Life Tables; As presented by Dr. Elmariah in 2022 TCT Symposium: Treatment of Aortic Stenosis by age in the U.S.: Evidence of institutional ageism

This is What 80 Looks Like...



Indiana Jones 5 Star Left in Awe of Harrison Ford: 'Age Ain't Nothing But a Number to This Man'

Indiana Jones 5 star Boyd Holbrook heaps praise on Harrison Ford.

BY JONATHAN FUGE
PUBLISHED 5 DAYS AGO



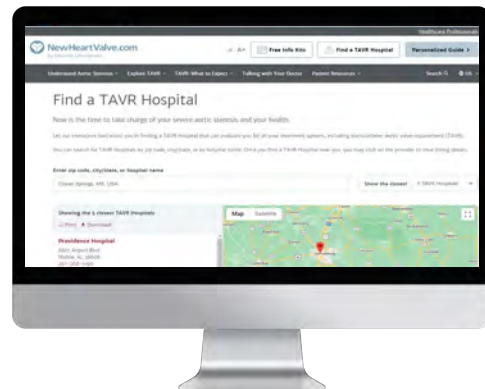
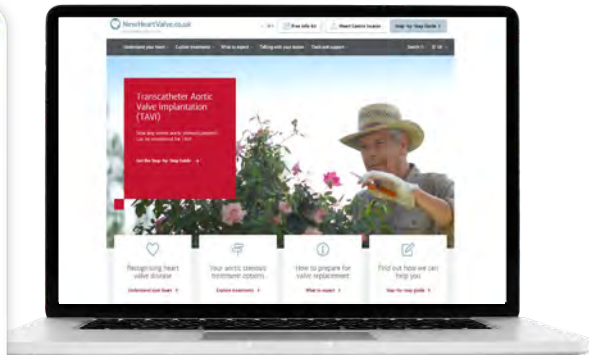
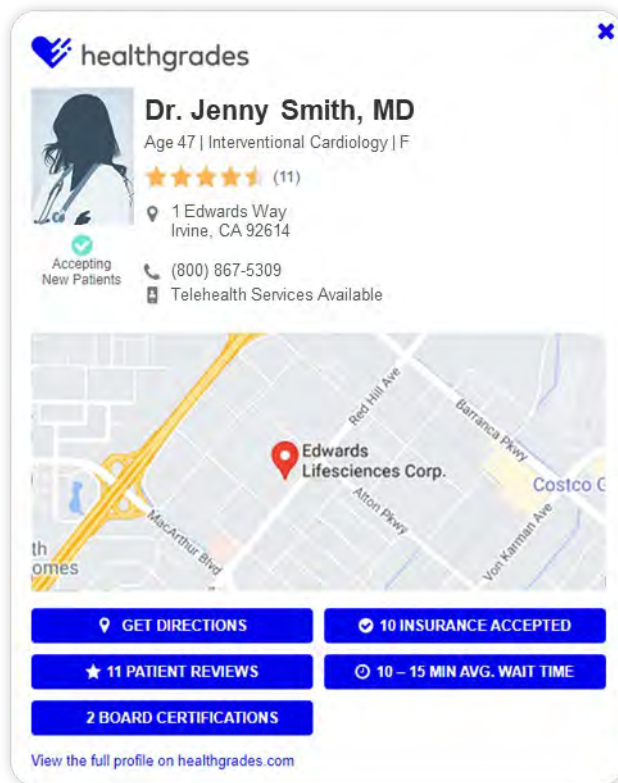
If Indiana Jones were diagnosed with Severe AS, he would deserve a TAVR!



© 2022 Harrison Ford by Gage Skidmore is licensed under [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/)



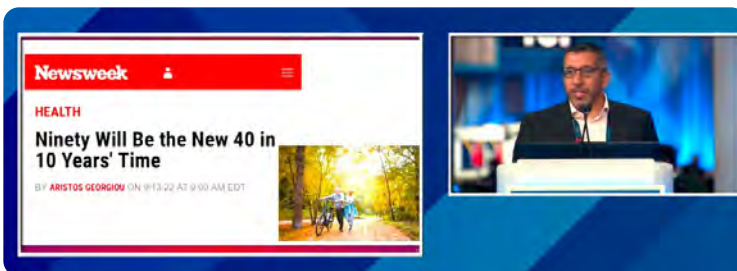
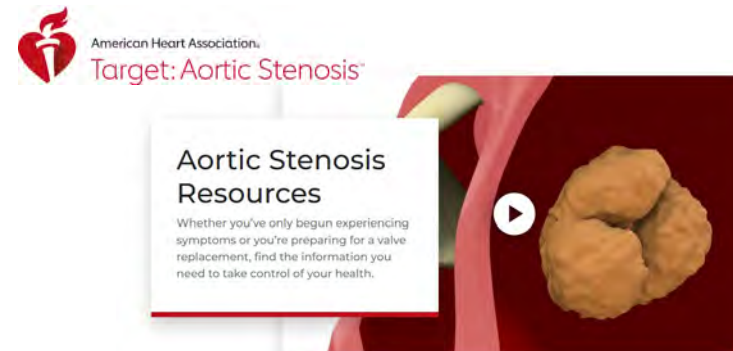
Our immediate focus: Improve therapy penetration in 80+ cohort by engaging patients and referrers through our global digital and media strategy



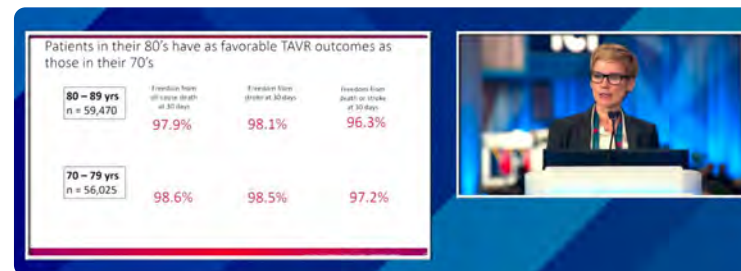
Our immediate focus: Engage with the clinical community through scientific education to address undertreatment head-on



2022 TCT Symposium Moderated by David A. Wood;
Faculty: Evelio Rodriguez, Megan Coylewright, Sammy Elmariah



Dr. Sammy Elmariah, 2022 TCT Symposium: Treatment of Aortic Stenosis by age in the U.S.: Evidence of institutional ageism



Dr. Megan Coylewright, 2022 TCT Symposium: Results and benefits of transcatheter aortic valve intervention in the U.S. by age

Edwards is supporting a quality-of-care initiative led by AHA

The **American Heart Association** and Edwards have a shared goal of lowering cardiovascular mortality, specifically by “establishing and advancing a new standard of care in structural heart disease”



American Heart Association®

Target: Aortic Stenosis™

80

**hospitals
in next
3 years**



Hospital Systems

Implement **quality measures** to ensure patients are treated in accordance to guidelines in a timely manner

1

2



HCPs

Professional education

3



Patients

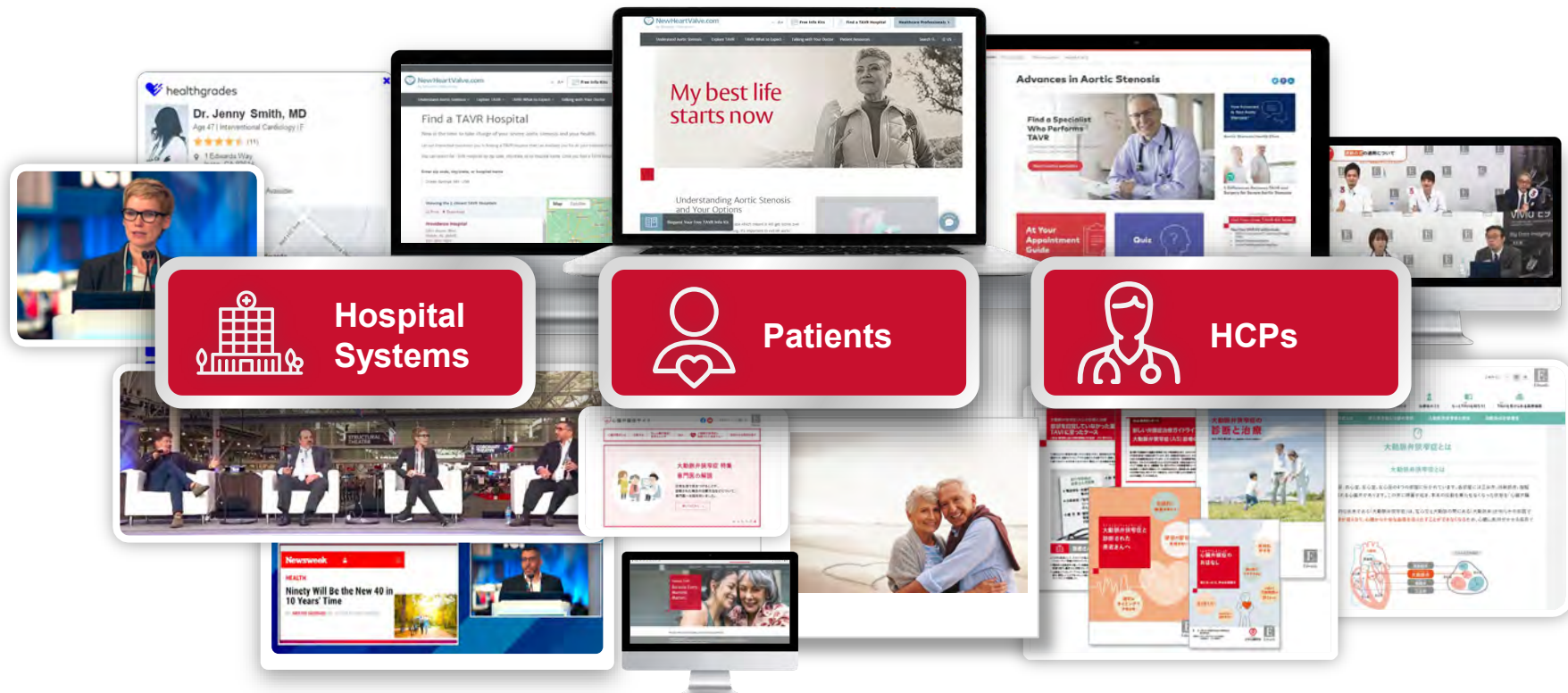
Awareness & engagement



Edwards Lifesciences is the national sponsor of American Heart Association's Target: Aortic Stenosis

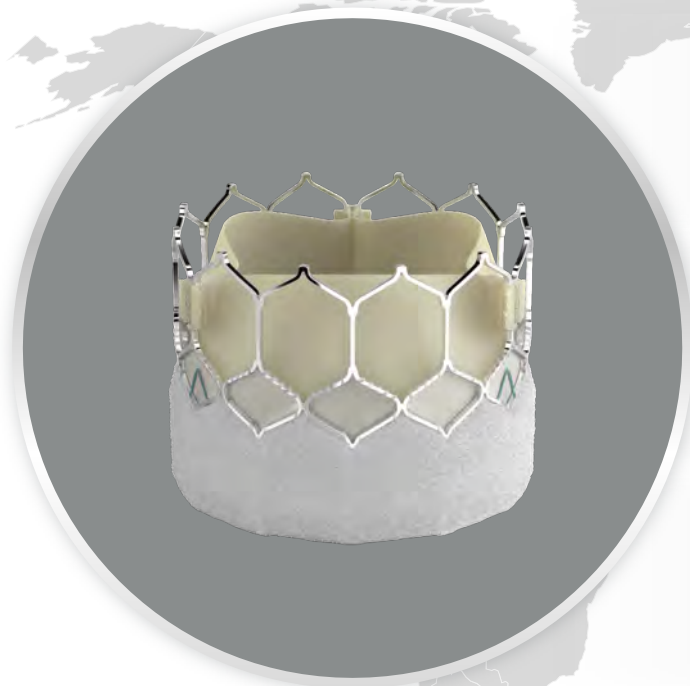
Website: www.heart.org/TargetAS

We believe that a combination of all of these activities will have a meaningful impact on immediate challenges and therapy adoption



Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

Key Pillars of Our Strategy



**Increase Therapy Adoption
in Growing AS Opportunity**



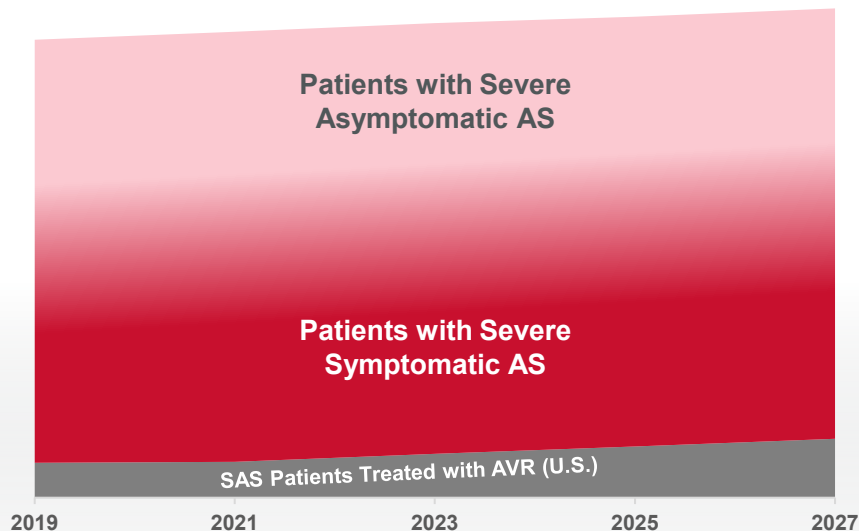
Expand Indications



**Deliver Strong
Portfolio Innovation**

Long term, we continue to build evidence to further expand our leadership within the severe AS opportunity

Severe AS Opportunity in U.S.



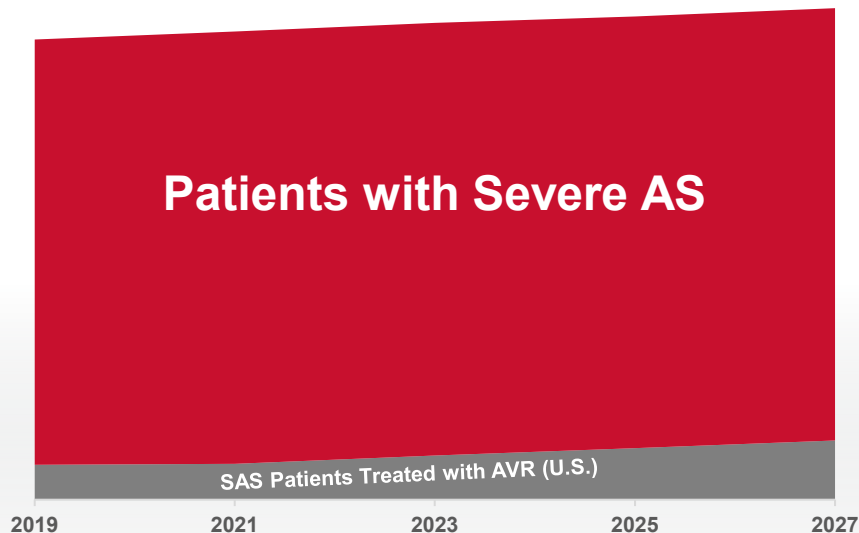
- Significant number of severe AS patients are **perceived** asymptomatic
- Symptoms are unnoticed, ignored, or associated with general aging
- Providers fail to elicit symptoms in patients during office visit

With EARLY TAVR, we are still only addressing severe AS patients

Severe AS Opportunity in U.S.



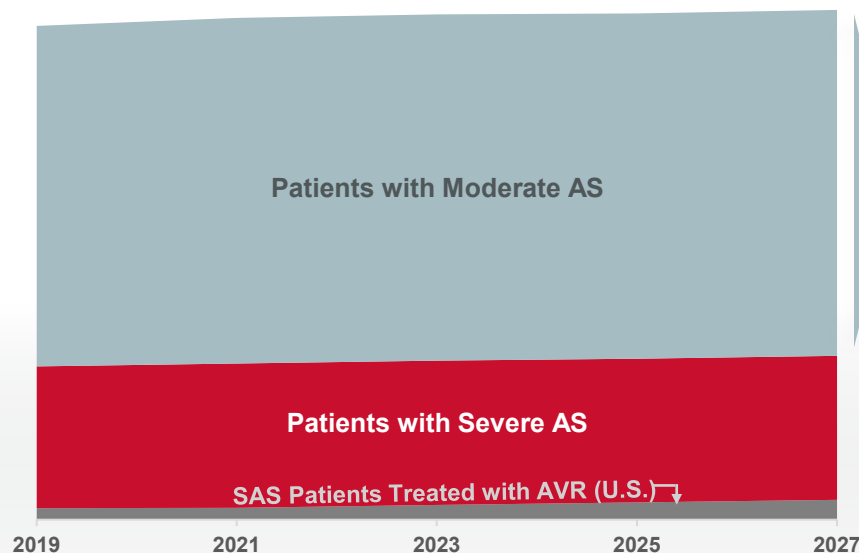
Patients with Severe AS



- EARLY TAVR trial will help us understand if intervention should occur before symptoms develop
- Enrollment completed in 2021
- Currently, in follow-up (2-year primary endpoint)

While the severe AS opportunity is significant, moderate AS adds new frontier for growth

Moderate-to-Severe AS Opportunity in U.S.



2:1

Ratio of
Moderate to
Severe AS
patients¹



- The PROGRESS Trial will help us understand the true impact of Moderate AS and the optimal time of intervention before damage to the heart occurs
- Currently enrolling

PROGRESS Trial Design



Moderate, calcific AS and appropriate anatomy for transfemoral TAVR

1:1 Randomization (n = 750)

TAVR
(SAPIEN 3/ SAPIEN 3 Ultra System)

Clinical surveillance

Potential delayed-AVR¹

Primary endpoint

Death, stroke and unplanned CV² rehospitalization at 2 years

Follow-up

Annually through 10 years

Contemporary data shows moderate AS patients have similarly poor prognoses as severe AS patients



Moderate, calcific AS and appropriate anatomy for transfemoral TAVR

1:1 Randomization (n = 750)

TAVR
(SAPIEN 3/ SAPIEN 3 Ultra
System)

Clinical surveillance

Potential delayed-AVR¹

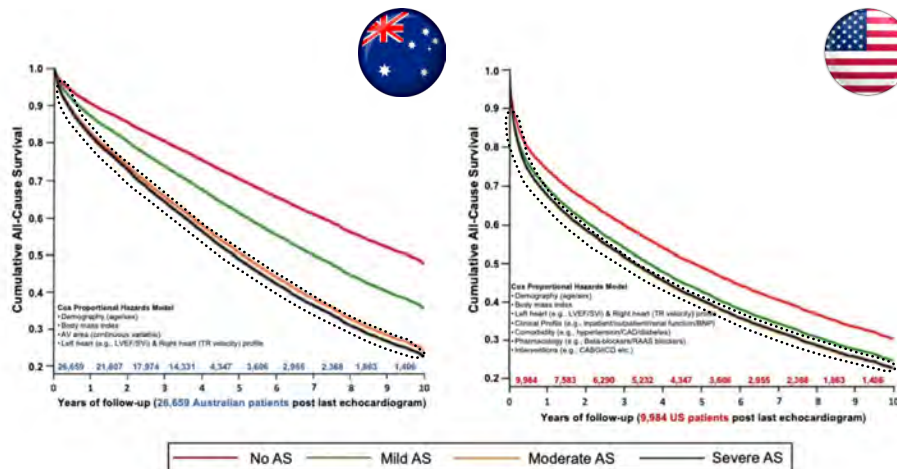
Primary endpoint

Death, stroke and unplanned CV² rehospitalization at 2 years

Follow-up

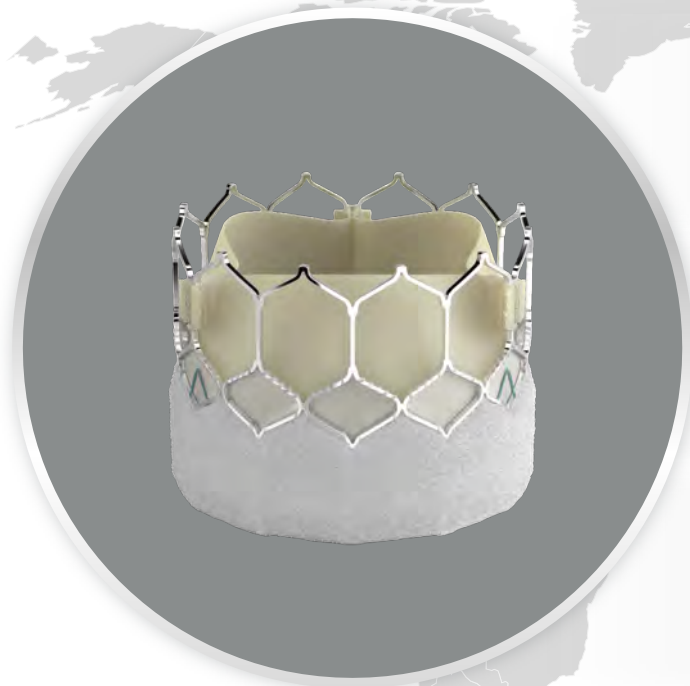
Annually through 10 years

Fully adjusted all-cause mortality
according to AS stage³



Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

Key Pillars of Our Strategy



Increase Therapy Adoption
in Growing AS Opportunity



Expand Indications



Deliver Strong
Portfolio Innovation

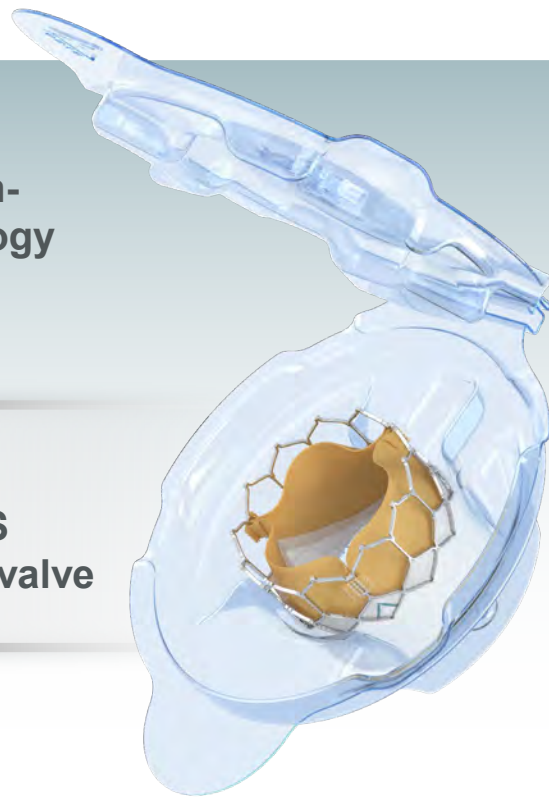
Our future portfolio further elevates TAVR and the benchmark of lifetime management



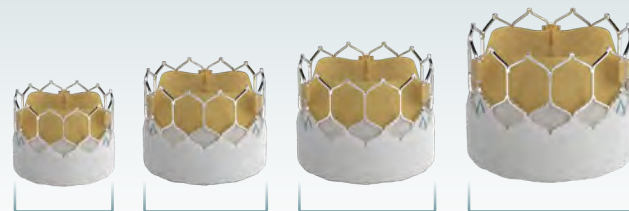
The first step in further elevating the TAVR therapy is the launch of SAPIEN 3 Ultra RESILIA system

Advanced **calcium-blocking technology**

RESILIA Tissue:
Same as INSPIRIS
RESILIA surgical valve



The only THV with
dry tissue storage



**Enhanced PVL skirt for all
valve sizes (including 29mm)**

Our Next Generation Technology: SAPIEN X4 Transcatheter Heart Valve System

Novel Frame and
Leaflet Design to Enable
Adjustable Sizing

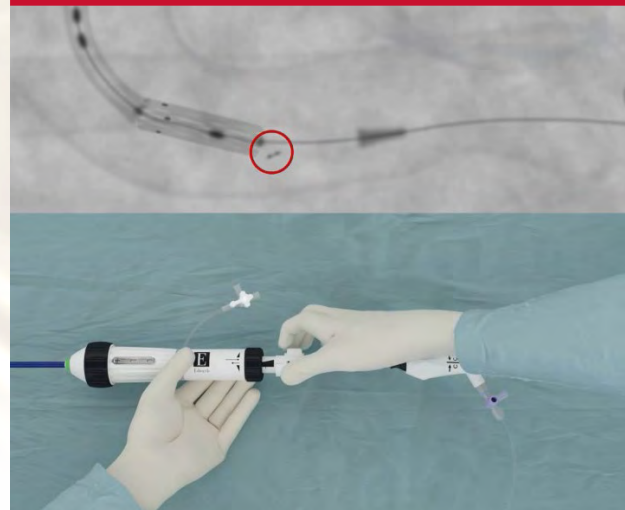
Frame Design to Facilitate
Future Coronary Access

Advanced PET Outer
Skirt Technology

RESILIA Tissue

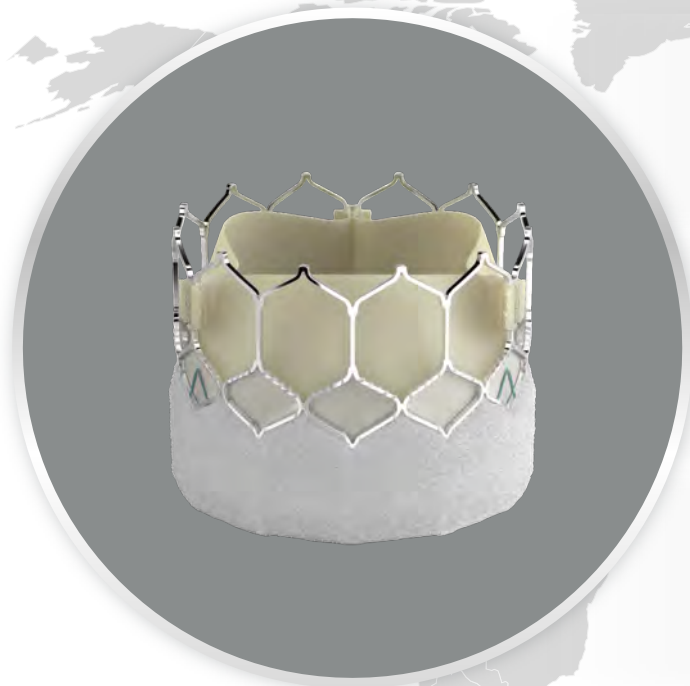


Advanced Delivery System
Technology Offers
Commissural Alignment



Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

Key Pillars of Our Strategy



**Increase Therapy Adoption
in Growing AS Opportunity**



Expand Indications



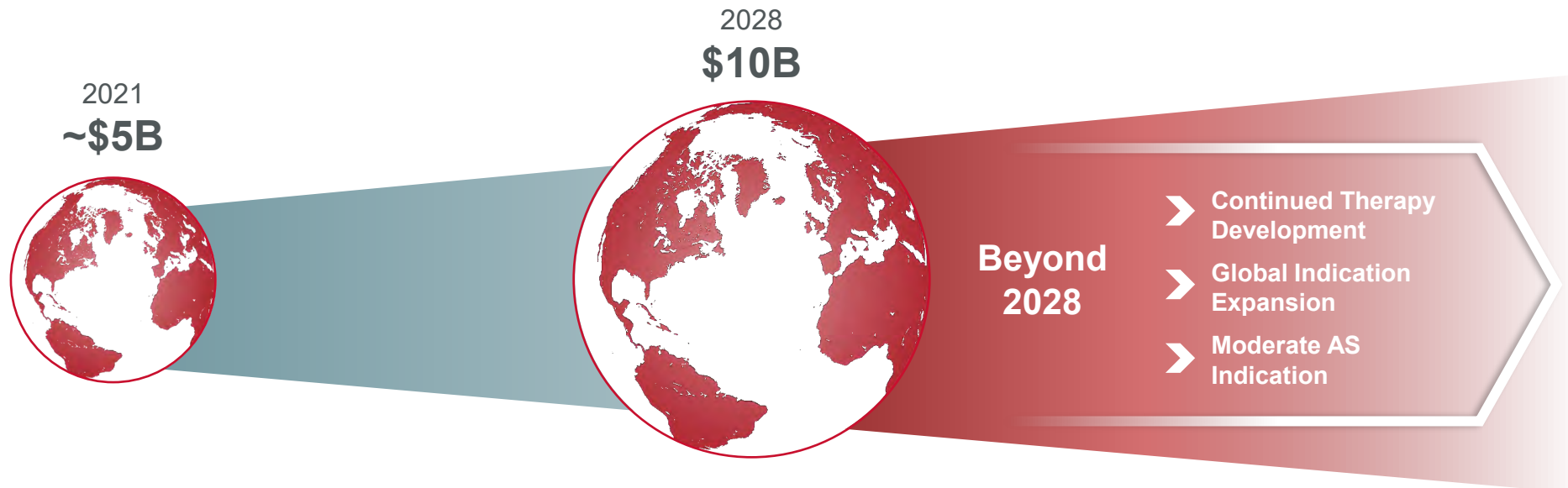
**Deliver Strong
Portfolio Innovation**

We remain confident in our view that the global TAVR opportunity will double by 2028



The fundamentals of TAVR remain strong and the opportunity ahead is significant

And growth drivers beyond the plan horizon remain strong



The fundamentals of TAVR remain strong and the opportunity ahead is significant

2023 Underlying Global Sales Growth Outlook

Headwinds



Ongoing healthcare staffing recovery



COVID uncertainties

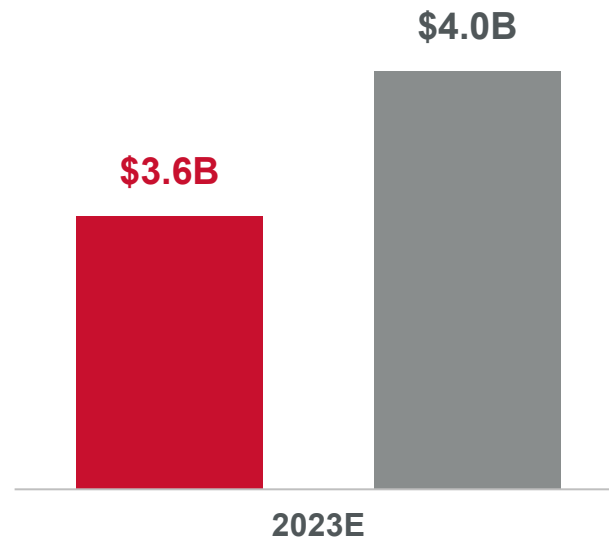
Tailwinds



Increasing therapy adoption in a rapidly growing elderly population



Potential patient backlog



Underlying **Global TAVR** Estimated Sales Growth **9 – 12%**

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

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

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

Contraindications: The valves and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections, or who have significant annuloplasty ring dehiscence.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing prostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken or the storage solution does not completely cover the valve (SAPIEN 3 and SAPIEN 3 Ultra only), the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution (SAPIEN 3 and SAPIEN 3 Ultra only), rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Do not perform stand-alone balloon aortic valvuloplasty procedures in the INSPIRIS RESILIA aortic valve for the sizes 19-25 mm. This may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial annuloplasty ring dehiscence due to high risk of PVL. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial (incomplete) annuloplasty rings in the absence of annular calcium due to increased risk of valve embolization. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of rigid annuloplasty rings due to increased risk of PVL or THV deformation.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. If a significant increase in resistance occurs when advancing the catheter through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications. As compared to SAPIEN 3, system advancement force may be higher with the use of SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA THV in tortuous/challenging vessel anatomies. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium preventing safe transseptal access. Special care must be exercised in mitral valve replacement to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; pre-existing prosthetic ring in the tricuspid position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick > 5 mm), protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; access characteristics that would preclude safe placement of the Edwards sheath, such as severe obstructive calcification or severe tortuosity; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing prosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireframe frame fracture, annuloplasty ring dehiscence); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage. For left/right axillary approach, ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery. Residual mean gradient may be higher in a "THV-in-failing prosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting prosthesis be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; thoracic bleeding; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury or brachial plexus injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent

Indications: The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation as measured by echocardiography who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for pulmonary valve replacement.

Contraindications: The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. The physician must verify correct orientation of the valve prior to its implantation; the inflow (outer skirt end) of the valve should be oriented towards the proximal end (handle) of the delivery system to prevent the risk of severe patient harm. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Do not use the valve if the tamper evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or the expiration date has elapsed. Do not add or apply antibiotics to the storage solution, rinse solutions or to the valve.

Precautions: Long-term durability has not been established for the device. Regular medical follow-up is advised to evaluate device performance. Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials may have an allergic reaction to these materials. Accelerated deterioration of the valve may occur in patients with an altered calcium metabolism. Assessment for coronary compression risk prior to implantation is recommended. Patient venous anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. Patient radiation dose should be monitored during the procedure. Glutaraldehyde may cause irritation of the skin, eyes, nose and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Material Safety Data Sheet available from Edwards Lifesciences. Patient should be heparinized to maintain the ACT at ≥ 250 sec prior to introduction of the delivery system in order to prevent thrombosis. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Device recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without antiplatelet therapy. It is recommended that all device recipients be prophylactically treated for endocarditis to minimize the possibility of prosthetic valve infection. Correct sizing of the prestent into the RVOT is essential to minimize risks such as paravalvular leak, migration, embolization, and/or RVOT rupture. If a prestent fracture is detected with significant loss in valve functionality, reintervention should be considered. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: blood dyscrasias defined as: leukopenia, acute anemia, thrombocytopenia, or history of bleeding diathesis or coagulopathy; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated; positive urine or serum pregnancy test in female patients of childbearing potential.

Potential Adverse Events: Potential risks associated with the anesthesia, interventional procedure, and imaging include but are not limited to death; stroke/transient ischemic attack; respiratory insufficiency or respiratory failure; cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium, or valvular structures, including rupture of the RVOT that may require intervention; pericardial effusion/cardiac tamponade; cardiac failure; embolic event: air, calcific material, thrombus, device fragments; infection, including incisional site infection, septicemia, and endocarditis; myocardial infarction; renal insufficiency or renal failure; conduction system injury; arrhythmia; deep vein thrombosis; arteriovenous (AV) fistula; systemic or peripheral nerve injury; systemic or peripheral ischemia; pulmonary edema; pneumothorax; pleural effusion; dyspnea; atelectasis; dislodgement of previously implanted devices (i.e. pacing lead); blood loss requiring transfusion; anemia; radiation injury; electrolyte imbalance; hypertension or hypotension; allergic reaction to anesthesia, contrast media, antithrombotic therapy, device materials; hematoma or ecchymosis; syncope; pain; exercise intolerance or weakness; inflammation; angina; fever. Potential risks, that may or may not require intervention, associated with the valve, pre-stent, delivery system, and/or accessories include, but may not be limited to, the following: cardiac arrest; cardiogenic shock; coronary flow obstruction/transvalvular flow disturbance; device thrombosis; injury to tricuspid valve; device fracture; device embolization; device acute migration or malposition; endocarditis; chest pain/discomfort; hemolysis/ hemolytic anemia; device penetration/perforation into surrounding vasculature; device dysfunction (regurgitation and/or stenosis); aortic root distortion; embolic events: device fragments; mechanical failure of delivery system, and/or accessories.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information.

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Edwards SAPIEN 4 Transcatheter Heart Valve System

**CAUTION – Investigational Device. Limited by Federal (United States) law to investigational use.
This device is not available for marketing or commercial sale.**

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Edwards



Edwards

Helping Patients is Our Life's Work, and

life is now

EXHIBIT 64



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Tweet

Justin Levisay
@jlevismd

Most difficult/nuanced decisions about TAVR seem to increasingly revolve around lifetime management. Great case in 65 year old bicuspid with first Sapien Ultra RESELIA TAVR in Chicagoland and my partner @mj_ricciardi first TMVR with RESILIA. Dry storage and anti-Ca### leaflets



4:35 PM · Oct 13, 2022 · Twitter for iPad

5 Retweets · 2 Quote Tweets · 35 Likes



Dr. Gilbert Tang @GilbertTangMD · Oct 13

Replying to @jlevismd and @mj_ricciardi
Nice! On top of tissue technology optimal #TAVR Expansion is also key for durability. See @CircAHA paper by @JoaoLCavalcante @bapat_savrtavr @psoraja et al

1



7



João Cavalcante @JoaoLCavalcante · Oct 15

Replying to @GilbertTangMD @jlevismd and 4 others
Thank you @GilbertTangMD



2



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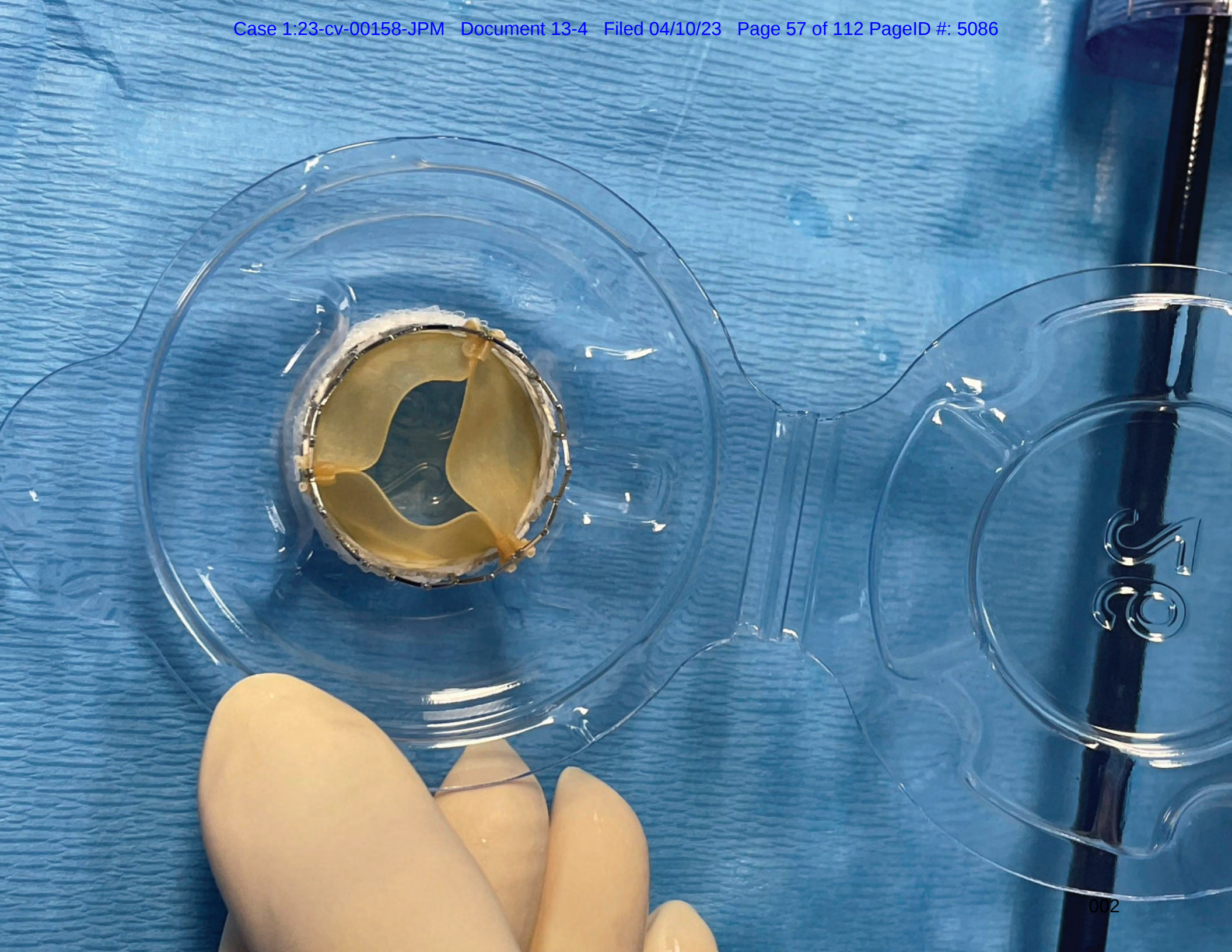




EXHIBIT 65



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NEWS

New Non-Surgery Heart Valve

September 28, 2020



Luis Delarosa enjoys doing physically demanding outdoors projects at home in Slatington, sometimes working from sunrise to sunset in the fresh air. Having been a landscaper for his entire adult life, the 76-year-old

Slatington man figured the fatigue and shortness of breath came with his

age and work, which he continues in retirement.

So, when his doctors said his aortic valve was failing, he put off having it treated as long as possible.

His doctors told him a buildup of calcium on his valve was preventing it from opening and closing efficiently, and he needed to have it replaced before serious complications might arise. The aortic valve is the gateway of blood between the heart and the rest of the body. Blood leaving the heart through the valve feeds supplies nutrients and oxygen to the brain and other organs. A damaged or diseased valve reduces this flow.

Earlier this year, St. Luke's University Health Network's Chair of Cardiovascular Medicine Raymond Durkin, MD, and Chief of Cardiovascular Surgery Stephen Olenchock, DO, inserted a newly FDA approved Sapien 3 ULTRA aortic valve into Delarosa's original diseased valve using a catheter introduced through a small incision in his groin. This was the first time the Sapien 3 ULTRA transcatheter aortic valve was used in the Greater Lehigh Valley region.

The Sapien 3 ULTRA valve was approved in by the FDA in 2019 for treating patients with severe aortic stenosis who, like Luis, are at a low risk for complications from open surgery. This newly designed valve from Edwards Lifesciences is easier and quicker to implant and made of newer, stronger materials.

In the PARTNER 3 clinical research trial, which preceded FDA approval, the Sapien 3 ULTRA valve was associated with lower death and stroke rates than conventional aortic valves implanted using open- heart surgery. Patients receiving the catheter-based valve are often able to leave the hospital sooner and experience a higher quality of life than those undergoing surgery.

"The Sapien 3 ULTRA aortic valve, with its excellent safety profile and improved design, expands the therapy options for persons having severe aortic stenosis but who desire non-surgical valve replacement," says

Dr. Olenchock.

Delarosa was out of the hospital the next day and back on his feet in no time and with nearly no pain. Now he's enjoying the late-summer weather, keeping busy outside on his home projects. And thanks to his new aortic valve and his restored youthful energy, he's sure he'll find other chores to keep him on the move and out in the fresh air.



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EXHIBIT 66



Edwards SAPIEN 3 Ultra valve

Built on proven technology

[Home](#) > [Edwards SAPIEN 3 TAVI](#) > [Edwards SAPIEN 3 Ultra valve](#)

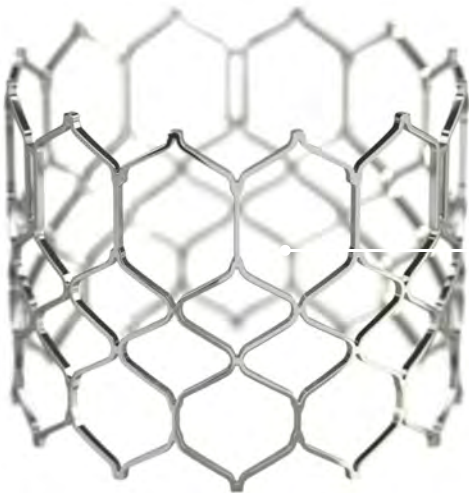
Advancing valve design

Built upon the proven SAPIEN platform, the SAPIEN 3 Ultra transcatheter heart valve is designed with your patient's future needs in mind.



Valve tissue

Uses same trusted bovine pericardium leaflet and ThermoFix anticalcification process as the Edwards SAPIEN 3 valve.



Enhanced geometric frame

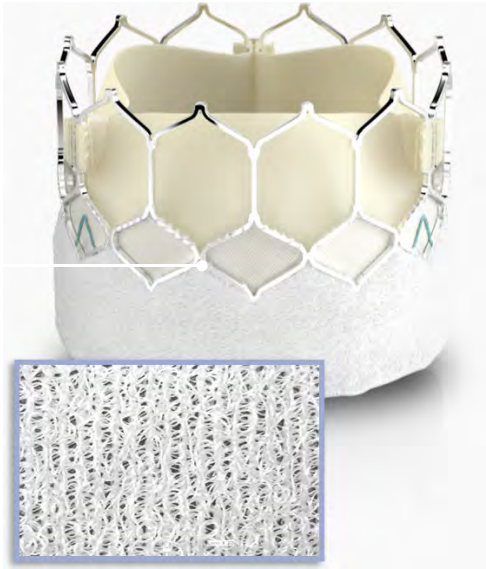
Low profile and open cell geometry facilitate coronary access.¹

Sealing skirt technology

Features a ~40% taller, textured polyethylene terephthalate (PET) outer skirt.*

*Compared to the Edwards SAPIEN 3 valve

Minimising paravalvular leak²



Textured fabric

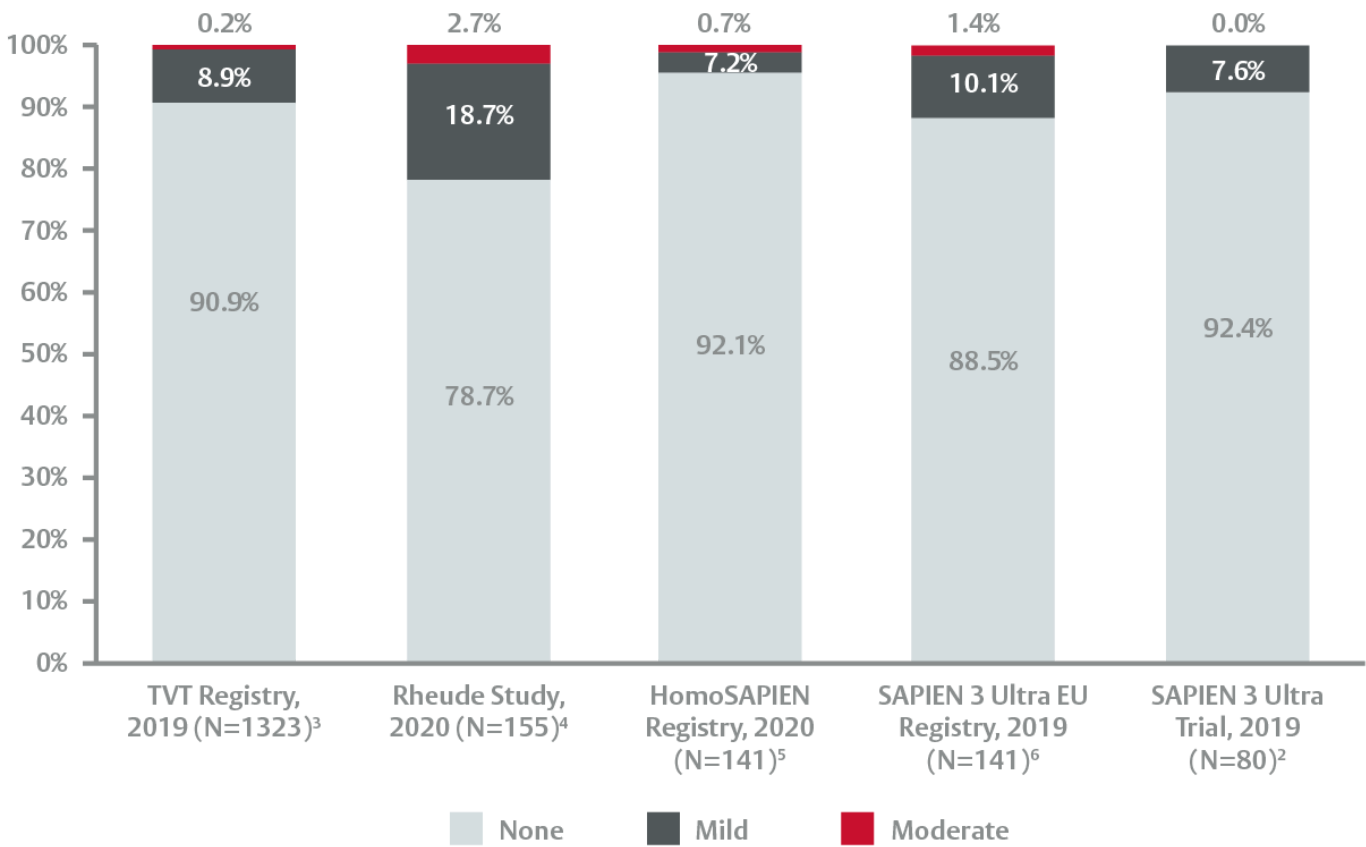
Important reductions in paravalvular leak (PVL)

Edwards SAPIEN 3 Ultra valve engineered to further reduce PVL

In the TVT Registry in over 1300 procedures:

- Edwards SAPIEN 3 Ultra valve eliminated severe PVL and produced close to zero levels of moderate PVL³
- Consistently low levels of mild PVL across the studies²⁻⁶

Moderate and severe PVL are independent predictors of 5-year all-cause mortality in multivariable analysis.⁷
Consistently low paravalvular leak rates at discharge^{3*}

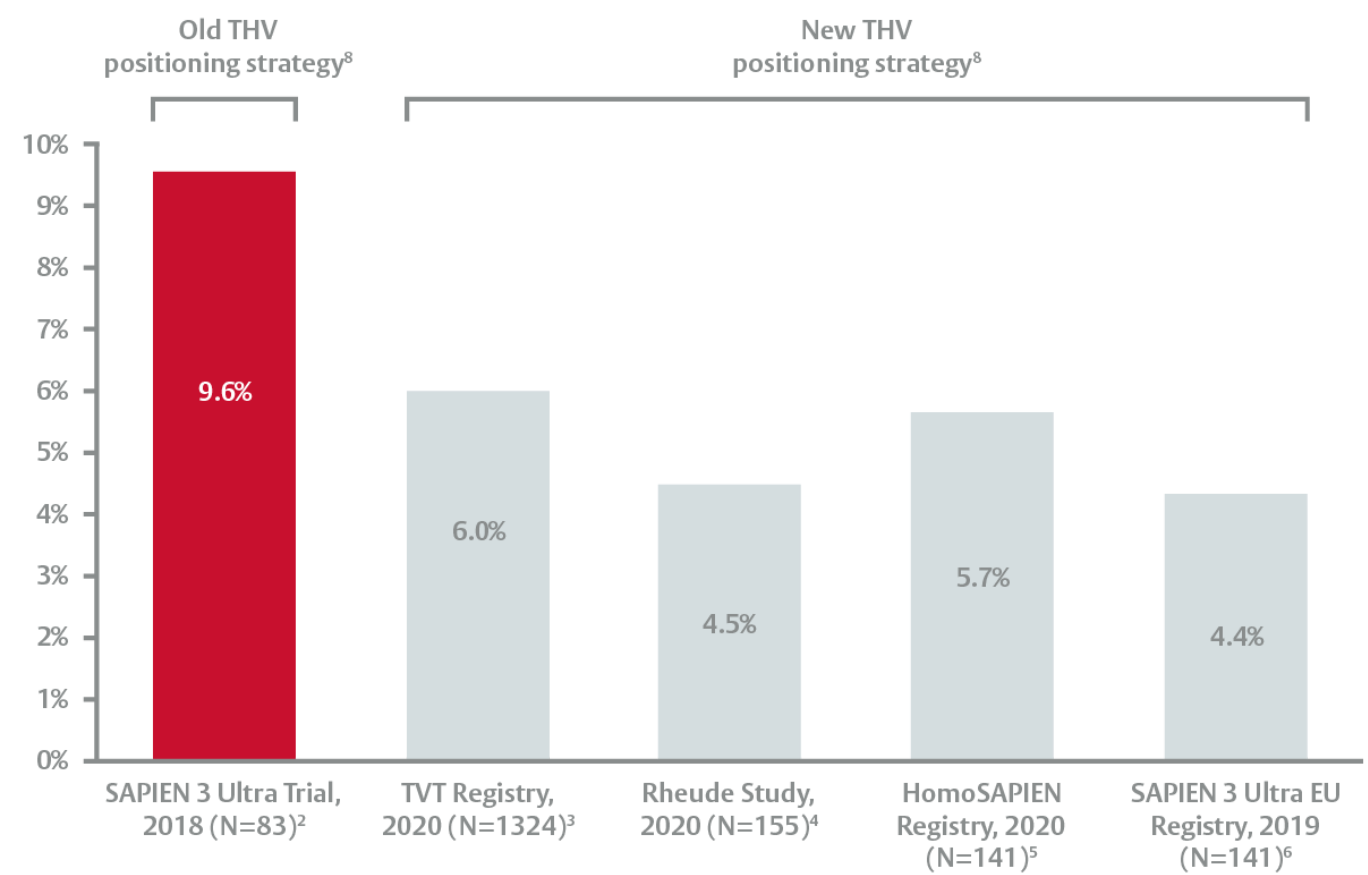


Single digit new permanent pacemaker rates

Low rates of new permanent pacemaker implantation (PPI) achieved with a high valve positioning strategy⁸

- New PPI is an independent predictor of mortality at 1 year⁹

Single digit new PPI rates at 30 days (including baseline)*

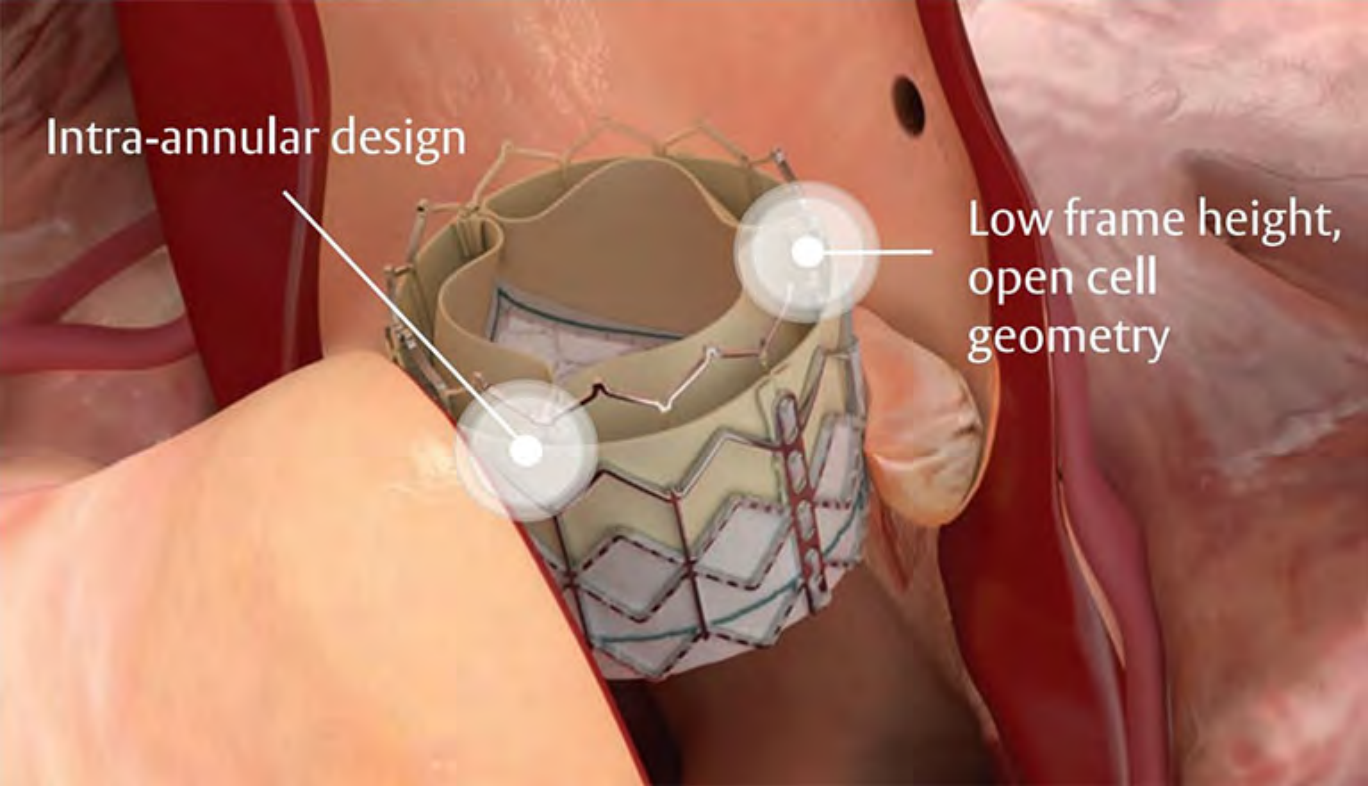


Today's transcatheter heart valve (THV) solution designed for lifetime patient management

Edwards SAPIEN 3 transcatheter aortic valve implantation (TAVI) is indicated for use in aortic and mitral redo procedures (including THV-in-THV)*

A lifesaving reintervention when TAVI is a preferred treatment option.

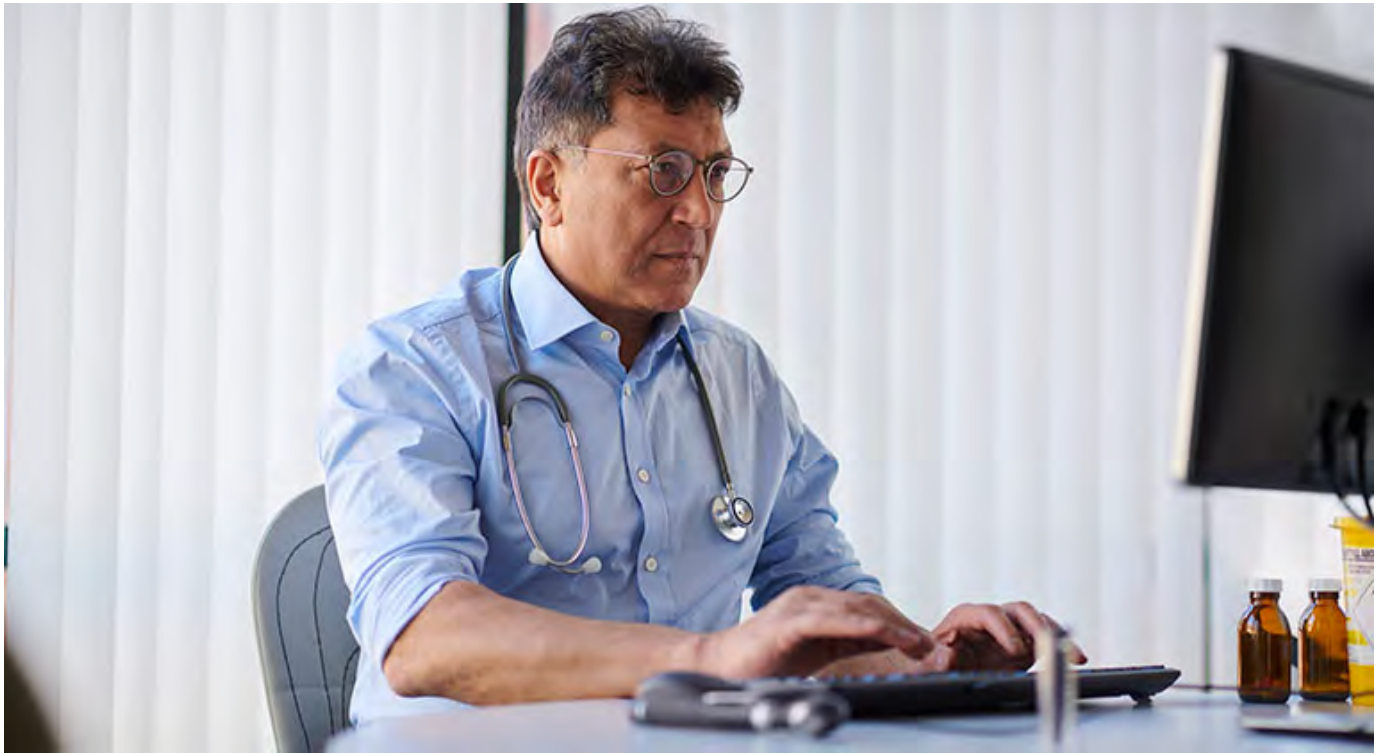
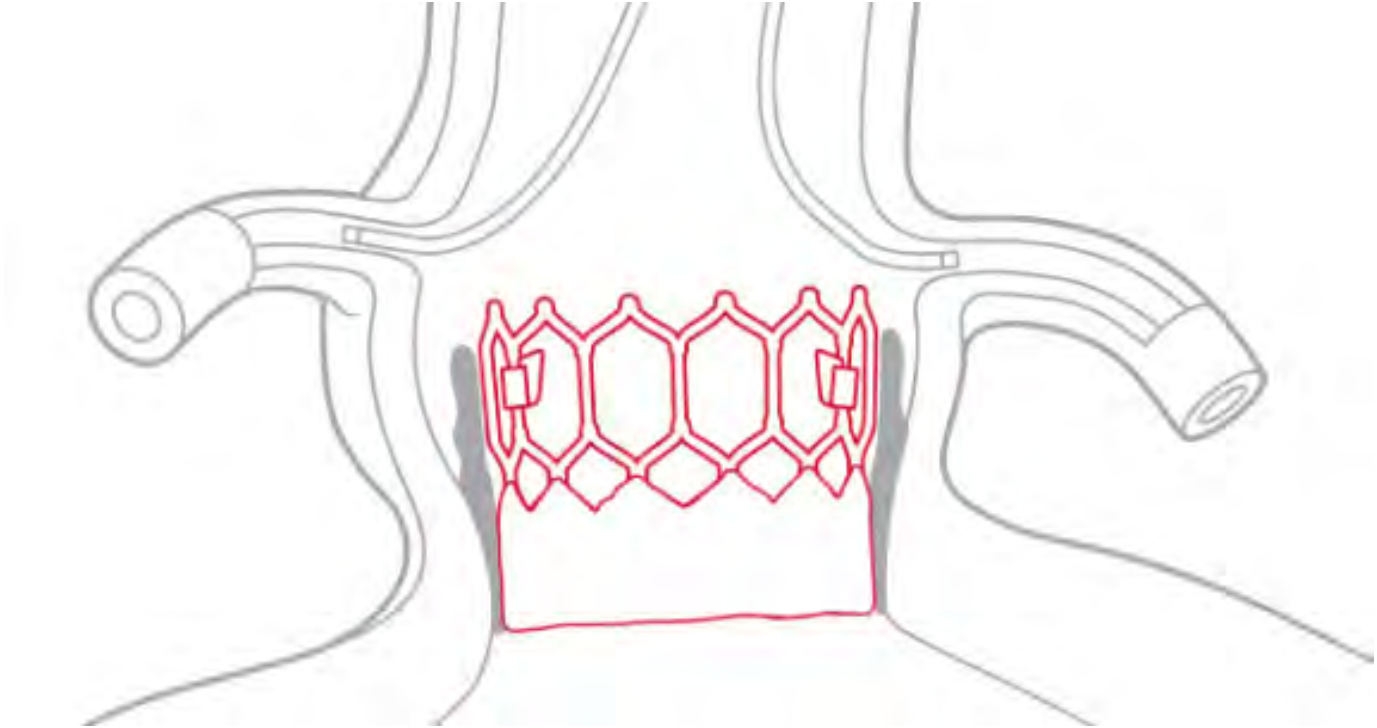
*For patients at high or greater surgical risk



Designed for future coronary access

Low profile frame design and open geometry facilitates future coronary access.¹

Registry data from SOURCE 3 showed 100% successful coronary access (n=61) post-TAVI.¹⁰



Edwards SAPIEN 3 Ultra valve Instructions for Use

See the Operator's Manual for all Edwards Lifesciences products.

[Visit Instructions for Use website](#) 

The Edwards COMMANDER delivery system

Designed to streamline the TAVI procedure and reduce complications with an ultra-low delivery profile, optimal positioning control and predictable deployment.

For predictable, proven results

Features of the Edwards COMMANDER delivery system:

- Stable, precise deployment delivering 99% first-time accuracy^{11†}
- Low delivery profile
- Dual articulation for coaxiality
- Optimal positioning control

[†]The PARTNER II Trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVI with the Edwards SAPIEN 3 valve, as-treated population (n=1078).¹¹



You refuse to compromise.

We couldn't agree more.

Find out more →

3D Sizing and Delivery System Guide

Edwards SAPIEN 3 Ultra valve is available in 3 sizes for maximum flexibility and optimal fitting.

Edwards SAPIEN 3 valve is also available in a 29mm size for larger annular diameters.

Edwards SAPIEN 3 Ultra valve size (mm)	3-D Area-derived Diameter (mm)	3-D Annular Area (mm ²)	Delivery System COMMANDER
20	18.6-21.0	273-345	14F e-Sheath
23	20.7-23.4	338-430	14F e-Sheath
26	23.4-26.4	430-546	14F e-Sheath

Edwards Lifesciences SAPIEN 3 Ultra TAVI procedural videos

Procedural guides on transfemoral access and Edwards SAPIEN 3 Ultra TAVI procedures:

01:53

Prendergast testimonial on valve design and coronary access (01:52)

Coronary access live action procedural demonstration.

02:20

balloon-expandable technology (02:19)

Transfemoral access procedure from insertion to deployment.

01:07

Edwards SAPIEN 3 Ultra valve — built for coronary access (01:06)

Edwards SAPIEN 3 Ultra valve coronary access and deployment procedure in detail.

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For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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EXHIBIT 67

From: Christy Lea <Christy.Lea@knobbe.com>
Sent: Thursday, October 13, 2022 5:01 PM
To: Geoffrey Smith; Joshua Stowell; began@mnat.com; araucci@morrisnichols.com; Vorder-Bruegge, Mark; Lubozynski, Matt; Lit EWLIFL.021L
Cc: apoff@ycst.com; John B. Campbell; Aortic-MS; Vrana, Robert
Subject: RE: Aortic Innovations v. Edwards - Protective order de-designation request

Geoff,

Edwards' Sapien 3 Ultra valve qualifies for AEO protection under the Protective Order. Its design reflects highly sensitive business information, the disclosure of which to Aortic and its prosecution attorneys is likely to cause significant harm to Edwards' IP position. While Edwards publishes images and videos of Sapien 3 Ultra, those do not reflect all of the design details that can be discerned or reverse engineered from the physical valve itself. Moreover, the commercial Sapien 3 Ultra is not readily available for close inspection, but rather is implanted in operating rooms under the watchful eye of Edwards' employees.

Here, Aortic seeks dedesignation of a demonstrative Sapien 3 valve that Edwards made and provided to facilitate the Court's understanding of the valve. It permits easy analysis of proprietary features of the valve that is not possible with a commercial SAPIEN 3 Ultra. For example, the demonstrative can easily be placed on a desk and studied indefinitely whereas a commercial SAPIEN 3 Ultra could not. If the demonstrative were effectively equivalent to a commercial SAPIEN 3 Ultra, and the commercial device were as publicly available as Aortic states, then Aortic would not be asking Edwards to de-designate the demonstrative. In this case, Edwards made a unique demonstrative to facilitate the litigation and now it appears that Aortic is trying to take advantage of Edwards' cooperation.

We are available to meet and confer on this issue on Friday. Please be prepared to address Aortic's need for a reduced confidentiality designation, especially given Aortic's contention that the published images and videos reflect the same information and the commercial device is publicly available.

Best,
Christy

Christy Lea
Partner
949-721-7642 Direct
949-500-6972 Cell
Knobbe Martens

From: Geoffrey Smith <gsmith@McKoolSmith.com>
Sent: Tuesday, October 11, 2022 6:37 PM
To: Joshua Stowell <Joshua.Stowell@knobbe.com>; began@mnat.com; araucci@morrisnichols.com; Vorder-Bruegge, Mark <m vb@wyattfirm.com>; Lubozynski, Matt <mlubozynski@wyattfirm.com>; Lit EWLIFL.021L <LitEWLIFL.021L@knobbe.com>
Cc: apoff@ycst.com; John B. Campbell <jcampbell@McKoolSmith.com>; Aortic-MS <Aortic-MS@McKoolSmith.com>;

EXHIBIT 68



Greg Brown • 2nd

Field Clinical Specialist II at Edwards Lifesciences

1d • 🌐

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[#tavr](#) [#technology](#) ...see more



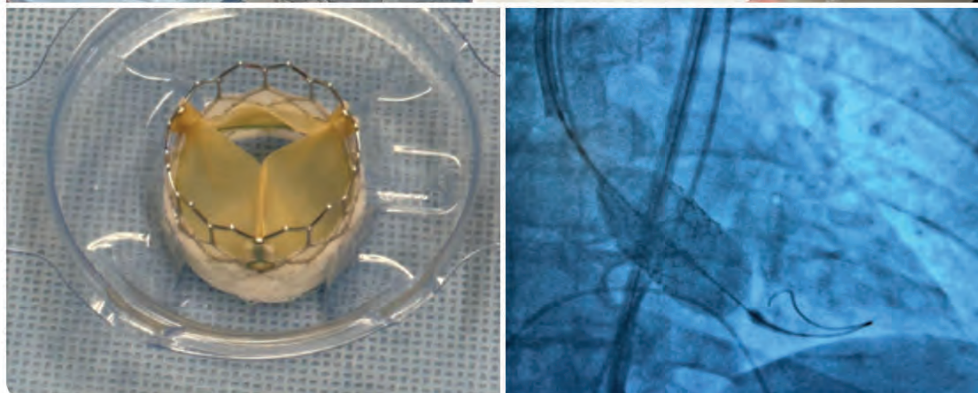
Mihir Barvalia, MD, MHA • 2nd

4d • 🌐

Launched new generation Edwards Sapien S3 Ultra Resilia Transcatheter Heart Valve !!

Thanks to Scripps LJ and Edwards team!

[#tavr](#) [#edwardslifesciences](#)



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EXHIBIT 69



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@Edwards_TAVR

Proudly providing the cardiology community with the latest insights and resources on all things TAVR. This page is intended for U.S. health care professionals.

📍 United States 🔗 us.heartvalves.com/resources 📅 Joined July 2019

93 Following 2,395 Followers

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Tweets & replies

Media

Likes

**Edwards TAVR** 🌟 @Edwards_TAVR · Feb 6

Deaths from [#HeartDisease](#) are higher in Black Americans than in White Americans and other ethnic groups. It is responsible for about 1 in every 4 male deaths and about 1 in every 5 female deaths. Help spread the word to your patients and loved ones.



226

**Edwards TAVR** 🌟 @Edwards_TAVR · Feb 6

Honor [#HeartMonth](#) and talk to your patients about [#HeartDisease](#). It is the #1 leading cause of death for men, women, and people of most racial and ethnic groups



1



246

**Edwards TAVR** 🌟 @Edwards_TAVR · Feb 3

Your patients are [#JustGettingStarted](#). February is [#HeartMonth](#). Nearly half of all adults in the United States have some type of cardiovascular disease and it affects people of different populations uniquely. Help spread awareness to your patients and loved ones today.



1



3

535

**Edwards TAVR** 🌟 @Edwards_TAVR · Jan 31

Time is valuable in the OR. Our tried and true Edwards Commander Delivery System keeps you efficient, delivering consistent deployment with 99% first-time accuracy.*

ow.ly/CgKS50JYumC

[#TAVR](#) [#medEd](#) [#hearthealth](#) [#cardioTwitter](#) [#heartnews](#) [#cardioEd](#) [#medTwitter](#)

Edwards Commander Delivery System
99% first-time accuracy*

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Important Safety Information
Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for use in patients with aortic stenosis who are not candidates for surgical aortic valve replacement.

1 6 753



Edwards TAVR @Edwards_TAVR · Jan 24

The **#SAPIEN3Ultra** valve is now powered by **#RESILIA** tissue, the same tissue technology used in the #1 implanted surgical valve in the US. The **#SAPIEN3UltraRESILIA** valve is taking **#TAVR** further, so your patients can go farther.

Learn more at ow.ly/sIY850KHbnU

#SAPIEN #THV



2 2 221



Edwards TAVR @Edwards_TAVR · Jan 20

Building on the benefits of the **#SAPIEN** platform which delivers superior outcomes for your patients, the **#SAPIEN3UltraRESILIA** valve is now powered by **#RESILIA** tissue. Together, we're taking **#TAVR** further.



Edwards TAVR

472 Tweets

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1 1 269



Edwards TAVR @Edwards_TAVR · Jan 13

RESILIA tissue is our proprietary tissue technology that uses a stable-capping process to block calcium from binding to the tissue.*1 This latest innovation offers a unique solution to take **#TAVR** further so your patients can go farther.

Learn more at ow.ly/pJgM50KHaZK



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87 views 0:09 / 1:43

1 3 286

**Edwards TAVR** @Edwards_TAVR · Jan 10

The next innovation in #TAVR is here. Introducing SAPIEN 3 Ultra RESILIA valve. Together, we're taking TAVR further.

Learn more at ow.ly/rYv350KHa8f

#RESILIA #takingTAVRfurther #SAPIEN3UltraRESILIA #cardiovascular #cardiotwitter



1 3 282

**Edwards TAVR** @Edwards_TAVR · Jan 6

The Edwards #SAPIEN3Ultra valve was designed to minimize PVL with a 40% taller, textured skirt compared to the Edwards #SAPIEN3 valve. Click to learn more about #SAPIEN3Ultra #TAVR.

ow.ly/ZhWq50JYtHm

#medEd #cardioTwitter #hearthealth #heartnews #medTwitter #patients



1 7 508

**Edwards TAVR** @Edwards_TAVR · Jan 3

Mod/severe paravalvular leak (PVL) is associated with increased mortality in severe #aorticstenosis patients post-#TAVR.* That's why we are proud to share that the #PARTNER3 Trial demonstrated only 0.6% mod/severe PVL at 1 year (similar to surgery!).

ow.ly/nEAb50JYtulTrending in United States
#millrosegamesTrending in United States
#SamsungxDIVETrending in United States
Rylan Griffen
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Subcutaneous analysis of the association between a baseline PVL and 1-year outcomes for the SAPIEN 3 PARTNER 3 trial.
1. Mack MJ, Leon VM, Pham VU, et al. Transcatheter aortic valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;381(18):1605-1705.

Important Safety Information
Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

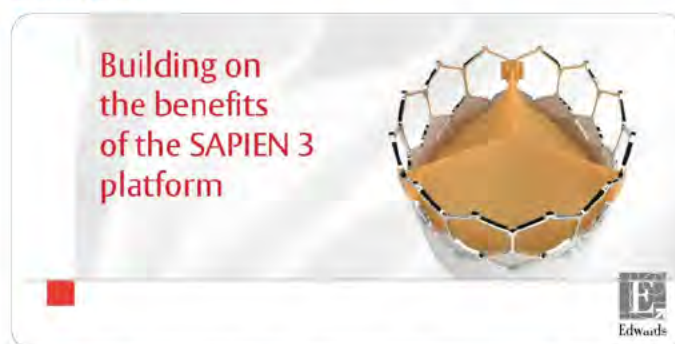
Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for aortic valve replacement in patients with aortic stenosis who are at high risk for aortic valve disease.

**Edwards TAVR** @Edwards_TAVR · Dec 30, 2022

A difference you can see, the #SAPIEN3UltraRESILIA valve is the only #THV with unique dry tissue storage.

Learn more about the latest #SAPIEN innovation at ow.ly/AgIj50KHbNX

#SAPIEN3Ultra #RESILIA #TAVR #takingTAVRfurther #cardiovascular #cardiotwitter



4 444

**Edwards TAVR** @Edwards_TAVR · Dec 20, 2022

We're happy to announce the 29mm valve size is now available and includes the same #PVL outer skirt technology as the rest of our #SAPIEN3UltraValves.

Learn more about the latest #SAPIEN innovation at ow.ly/2ejC50KHbA9

#SAPIEN3UltraRESILIA #TAVR #takingTAVRfurther #TAVR



2 5 418

**Edwards TAVR** @Edwards_TAVR · Dec 16, 2022

At #Edwards, your #patients are our priority. That's why #Edwards has been working hard across our #PARTNER trials to reduce paravalvular leak.

ow.ly/2h6q50JYuFV

#TAVR, #cardioTwitter, #medEd, #cardioEd, #medTwitter, #aorticstenosis, #heartnews, #hearthealth



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#SAPIEN #THV

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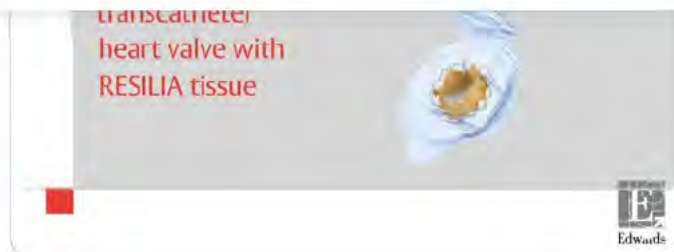
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Edwards TAVR @Edwards_TAVR · Nov 25, 2022

Building on the benefits of the #SAPIEN platform which delivers superior outcomes for your patients, the #SAPIEN3UltraRESILIA valve is now powered by #RESILIA tissue. Together, we're taking #TAVR further.

Learn more at ow.ly/lbzb50KHb95

#RESILIA #THV #takingTAVRfurther



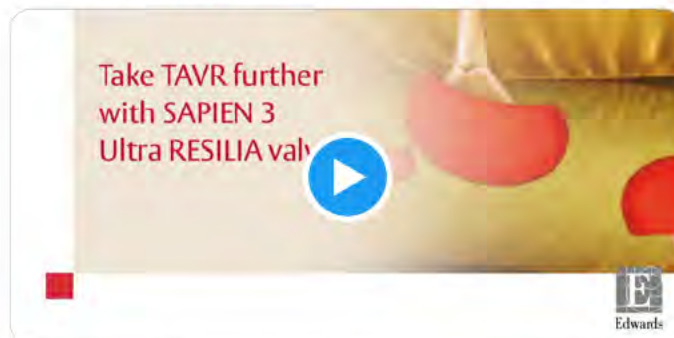
2 7



Edwards TAVR @Edwards_TAVR · Nov 18, 2022

RESILIA tissue is our proprietary tissue technology that uses a stable-capping process to block calcium from binding to the tissue.*1 This latest innovation offers a unique solution to take #TAVR further so your patients can go farther.

Learn more at ow.ly/pJgM50KHazK



1 1



Edwards TAVR @Edwards_TAVR · Nov 11, 2022

The next innovation in #TAVR is here. Introducing SAPIEN 3 Ultra RESILIA valve. Together, we're taking TAVR further.

Learn more at ow.ly/rYv350KH8f

#RESILIA #takingTAVRfurther #SAPIEN3UltraRESILIA #cardiovascular #cardiotwitter

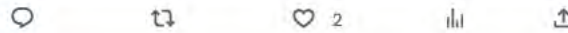
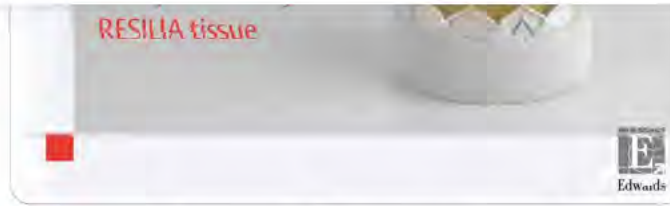
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Edwards TAVR @Edwards_TAVR · Nov 9, 2022

Edwards TAVR 472 Tweets

design to easily facilitate future access.

ow.ly/cj8J50JYub9

#TAVR #medTwitter #hearthealth #cardioTwitter #patients #heartnews

Edwards SAPIEN 3 Ultra valve

Important Safety Information
2:16 | 60 views

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for use in patients with aortic stenosis who are at high risk for surgical aortic valve replacement.

Twitter interaction icons: reply, retweet, like (2), bookmark, share



Edwards TAVR @Edwards_TAVR · Nov 4, 2022

In our ongoing commitment to minimize paravalvular leak (#PVL), the Edwards #SAPIEN3Ultra valve features a ~40% taller outer skirt compared to the Edwards #SAPIEN3 valve. Early PVL data shows 0% $\geq$ moderate leak at 30 days.

ow.ly/IJB50JYu4x

#TAVR #cardioTwitter #medEd

SAPIEN 3 Ultra Study paravalvular leak (PVL) at 30 days¹

0% $\geq$ moderate PVL at 30 days

Important Safety Information
Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for use in patients with aortic stenosis who are at high risk for surgical aortic valve replacement.

Twitter interaction icons: reply (1), retweet (5), like (12), bookmark, share



Edwards TAVR @Edwards_TAVR · Nov 1, 2022

How you manage your patients' severe aortic stenosis (#SAS) today can impact future #coronaryaccess. The good news is, the Edwards #SAPIEN3 valve is engineered for the future. Learn more.

ow.ly/nRNJ50JYtXj

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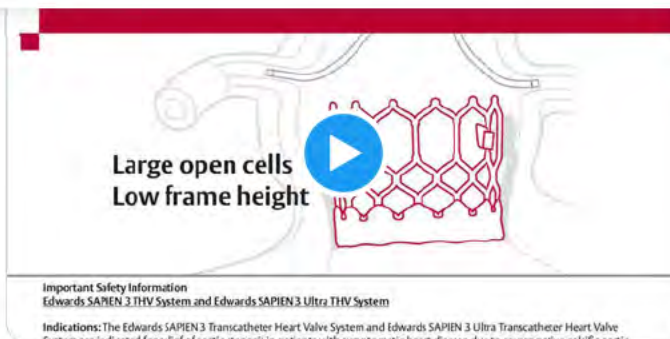
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1 5

Edwards TAVR Retweeted



Edwards Lifesciences @EdwardsLifesci · Oct 27, 2022

Thank you to the #PrixGalien committee for selecting the #SAPIEN3 Ultra #THV as Silver Jubilee award winner @GalienFdn.



1 6 19



Edwards TAVR @Edwards_TAVR · Oct 27, 2022

Mod/severe paravalvular leak (PVL) is associated with increased mortality in severe #aorticstenosis patients post-#TAVR.* That's why we are proud to share that the #PARTNER3 Trial demonstrated only 0.6% mod/severe PVL at 1 year (similar to surgery!).

ow.ly/nEAb50JYtul



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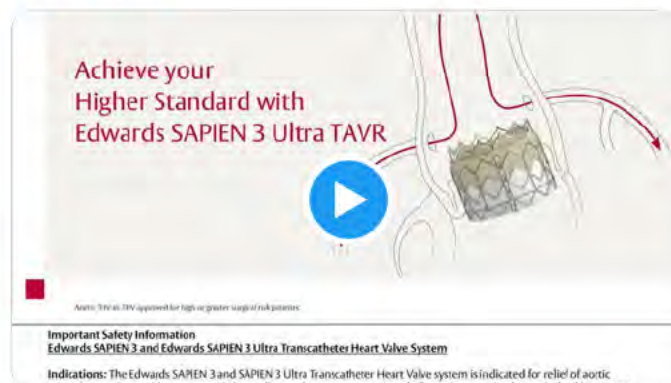
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Edwards TAVR @Edwards_TAVR · Oct 25, 2022

Thinking ahead to a second #TAVR when choosing the first valve is your Higher Standard. The Edwards #SAPIEN3Ultra valve is approved for #TAVRinTAVR and facilitates future coronary access, putting you in control of the lifetime management of your patients.

ow.ly/YTJL50JYsuz


2 3

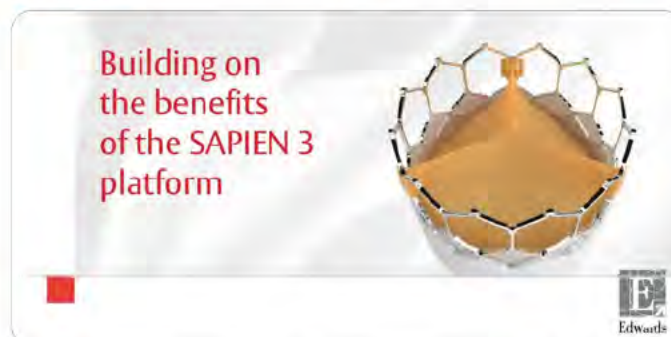


Edwards TAVR @Edwards_TAVR · Oct 21, 2022

A difference you can see, the #SAPIEN3UltraRESILIA valve is the only #THV with unique dry tissue storage.

Learn more about the latest #SAPIEN innovation at ow.ly/AgIj50KHbNX

#SAPIEN3Ultra #RESILIA #TAVR #takingTAVRfurther #cardiovascular #cardiotwitter



4 13



Edwards TAVR @Edwards_TAVR · Oct 14, 2022

We're happy to announce the 29mm valve size is now available and includes the same #PVL outer skirt technology as the rest of our #SAPIEN3UltraValves.

Learn more about the latest #SAPIEN innovation at ow.ly/2ejC50KHbA9

#SAPIEN3UltraRESILIA #TAVR #takingTAVRfurther #TAVR



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Edwards TAVR @Edwards_TAVR · Oct 12, 2022

At #Edwards, your #patients are our priority. That's why #Edwards has been working hard across our #PARTNER trials to reduce paravalvular leak.

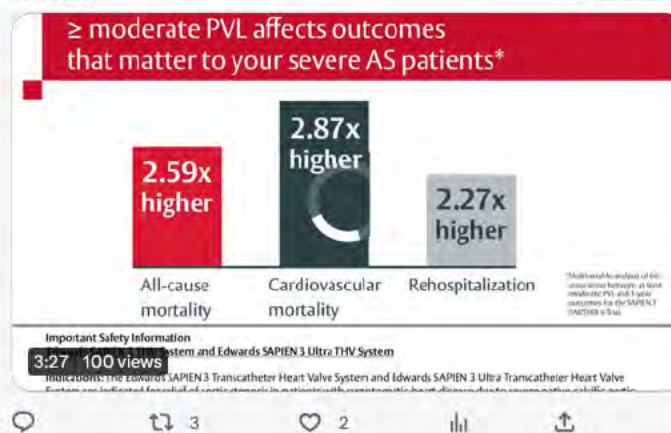
ow.ly/2h6q50JYuFV



Edwards TAVR

472 Tweets

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Edwards TAVR @Edwards_TAVR · Oct 7, 2022

With #lowrisk #patients in the #TAVR arena, future #coronaryaccess can't be an afterthought. Access to the coronary arteries post-TAVR w/the #SAPIEN3 valve was successful in 61/61 patients. The Edwards #S3Ultra valve is also designed w/the future in mind.

ow.ly/gOQS50JYuLZ



Edwards TAVR @Edwards_TAVR · Oct 4, 2022

We were proud to have been part of #picsymposium2022. If you weren't able to get your hands on the #Alterra adaptive prestant in our interactive booth experience, find out what you missed.

ow.ly/Me1x50KvT7T

⚠ Important Safety Info heartvalves.com/heart-team/isi...

#medEd #TPVR



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Time is valuable in the OR. Our tried and true Edwards Commander Delivery System keeps you efficient, delivering consistent deployment with 99% first-time accuracy.*

ow.ly/CgKS50JYumC

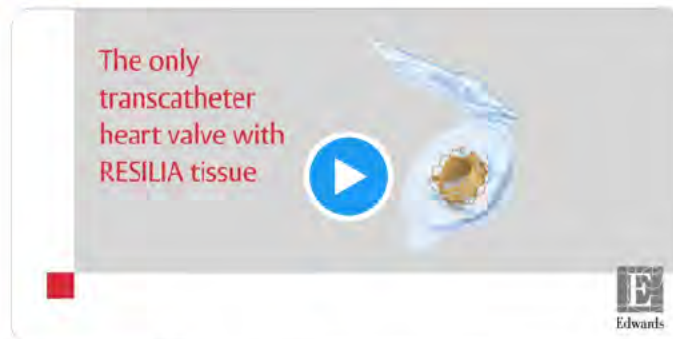
#TAVR #medEd #hearthealth #cardioTwitter #heartnews #cardioEd
#medTwitter



The #SAPIEN3Ultra valve is now powered by #RESILIA tissue, the same tissue technology used in the #1 implanted surgical valve in the US. The #SAPIEN3UltraRESILIA valve is taking #TAVR further, so your patients can go farther.

Learn more at [ow.ly/sly850KHbnU](https://openstax.org/r/sly850KHbnU)

#SAPIEN #THV



Building on the benefits of the #SAPIEN platform which delivers superior outcomes for your patients, the #SAPIEN3UltraRESILIA valve is now powered by #RESILIA tissue. Together, we're taking #TAVR further.

Learn more at [ow.ly/Ibzb50KHb95](https://openstax.org/r/ow.ly/Ibzb50KHb95)

#RESILIA #THV #takingTAVRfurther



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Edwards TAVR @Edwards_TAVR · Sep 16, 2022

RESILIA tissue is our proprietary tissue technology that uses a stable-capping process to block calcium from binding to the tissue.*1 This latest innovation offers a unique solution to take #TAVR further so your patients can go farther.

Learn more at ow.ly/pJgM50KHazK



4 8



Edwards TAVR @Edwards_TAVR · Sep 13, 2022

The next innovation in #TAVR is here. Introducing SAPIEN 3 Ultra RESILIA valve. Together, we're taking TAVR further.

Learn more at ow.ly/rYv350KH8f

#RESILIA #takingTAVRfurther #SAPIEN3UltraRESILIA #cardiovascular #cardiotwitter



6 21



Edwards TAVR @Edwards_TAVR · Sep 9, 2022

There's still time to explore our interactive booth experience at #picsymposium2022. Continue to put your patients first with the Edwards #SAPIEN3 #TPVR system with #Alterra adaptive preseat. ow.ly/K26750KvSBv

⚠ Important Safety Info heartvalves.com/heart-team/isi...

#heartnews



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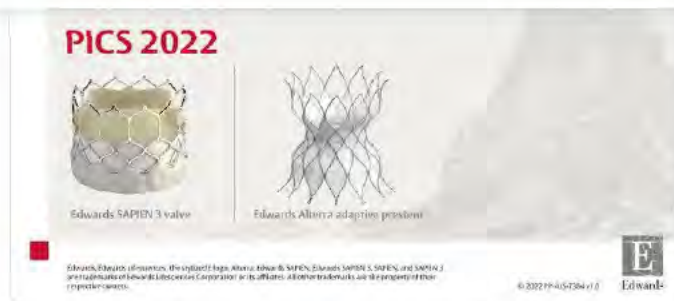
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**Edwards TAVR** @Edwards_TAVR · Aug 31, 2022

Join us at [#picsymposium2022](#) for the debut of a unique digital experience that puts the [#Alterra](#) adaptive presten at your fingertips. See you in Chicago!

[ow.ly/Xweo50KvTe4](#)

⚠ Important Safety Info [heartvalves.com/heart-team/isi...](#)

[#TPVR](#) [#pulmonic](#) [#heartnews](#) [#medEd](#) [#cardioTwitter](#)



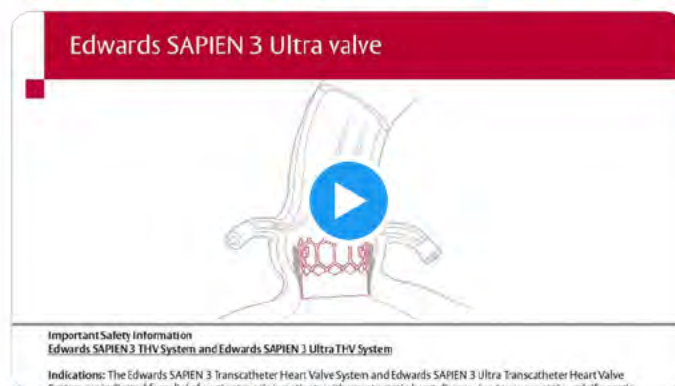
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**Edwards TAVR** @Edwards_TAVR · Aug 29, 2022

[#valvechoice](#) matters for future [#coronaryaccess](#). The Edwards [#SAPIEN3Ultra](#) valve was designed with a low frame height and large cell design to easily facilitate future access.

[ow.ly/cj8J50JYub9](#)

[#TAVR](#) [#medTwitter](#) [#hearthealth](#) [#cardioTwitter](#) [#patients](#) [#heartnews](#)



2 4

**Edwards TAVR** @Edwards_TAVR · Aug 27, 2022

In our ongoing commitment to minimize paravalvular leak ([#PVL](#)), the Edwards [#SAPIEN3Ultra](#) valve features a ~40% taller outer skirt

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#TAVR #cardioTwitter #medEd



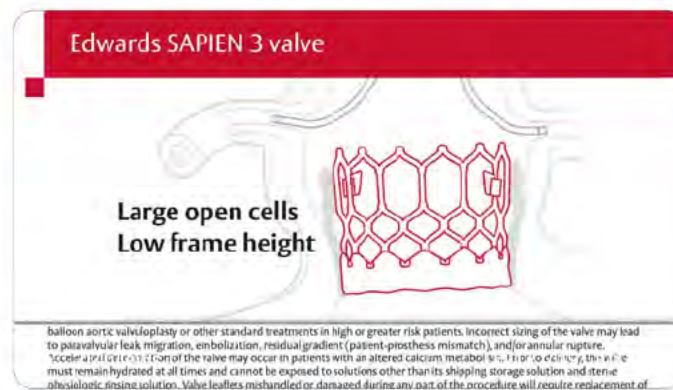
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**Edwards TAVR** @Edwards_TAVR · Aug 23, 2022

How you manage your patients' severe aortic stenosis (**#SAS**) today can impact future **#coronaryaccess**. The good news is, the Edwards **#SAPIEN3** valve is engineered for the future. Learn more.

ow.ly/nRNU50JYtXj

#cardioTwitter #hearthealth #medEd #heartnews #patients #TAVR

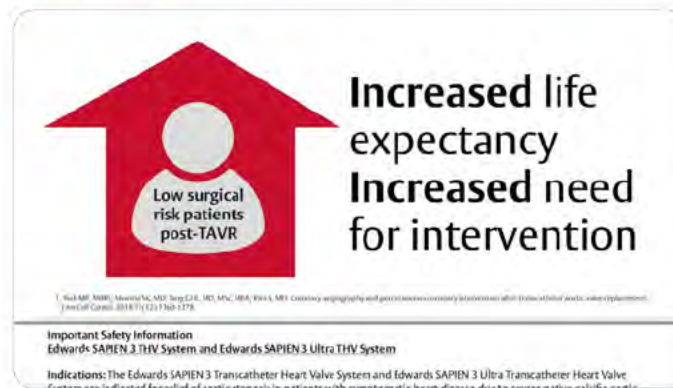


3 5

**Edwards TAVR** @Edwards_TAVR · Aug 20, 2022

Future **#coronaryaccess** matters in this new age of severe **#aorticstenosis**, marked by the inclusion of low surgical risk **#patients**. Learn about the transformational design of the Edwards **#SAPIEN3** valve & how it helps facilitate future coronary interventions.

ow.ly/rp6b50JYtPX



2 6

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#medEd #cardioTwitter #hearthealth #heartnews #medTwitter #patients

Edwards SAPIEN 3 Ultra valve
 40% taller, textured skirt*

Edwards TAVR

472 Tweets

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 SAPIEN 3 Ultra
 (2014)

 SAPIEN 3 Ultra
 (2018)

*Compared to the Edwards SAPIEN 3 valve.
are damaged (e.g., linked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the SAPIEN 3 Ultra Transcatheter Heart Valve system is not un-fused prior to removal. Care should be exercised to avoid injury to the coronary arteries, aorta, and other structures. The procedure should be performed by a physician experienced in transcatheter aortic valve replacement. The Edwards SAPIEN 3 Ultra Transcatheter Heart Valve system is not intended to be used in patients with aortic regurgitation, aortic dissection, or aortic aneurysm.


4

6


Edwards TAVR @Edwards_TAVR · Aug 11, 2022

Mod/severe paravalvular leak (PVL) is associated with increased mortality in severe #aorticstenosis patients post-#TAVR.* That's why we are proud to share that the #PARTNER3 Trial demonstrated only 0.6% mod/severe PVL at 1 year (similar to surgery!).

ow.ly/nEAb50JYtul
Edwards SAPIEN 3 valve

 Similar to
 surgery

0.6% ≥ moderate PVL at 1 year
 vs. 0.5% (surgery) (P=1.00)¹
*PARTNER3 trial analysis of the association between mod/severe PVL at 1 year post-TAVR and 1-year mortality in the SAPIEN 3 PARTNER 3 trial.
1. Mack MJ, Leon MB, Hougen CH, et al. Transcatheter paravalvular replacement with a balloon-expandable valve in bicuspid aortic stenosis. N Engl J Med. 2019;380(16):1605-1615.
Important Safety Information

Edwards SAPIEN 3 and Edwards SAPIEN 3 Ultra THV System

2:16 192 views

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve



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Edwards TAVR @Edwards_TAVR · Aug 8, 2022

Thinking ahead to a second #TAVR when choosing the first valve is your Higher Standard. The Edwards #SAPIEN3Ultra valve is approved for #TAVRinTAVR and facilitates future coronary access, putting you in control of the lifetime management of your patients.

ow.ly/YTJL50JYsuz

 Achieve your
 Higher Standard with
 Edwards SAPIEN 3 Ultra TAVR

Aortic, femoral, and iliofemoral approaches for high or greater surgical risk patients.
Important Safety Information

Edwards SAPIEN 3 and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve system is indicated for relief of aortic

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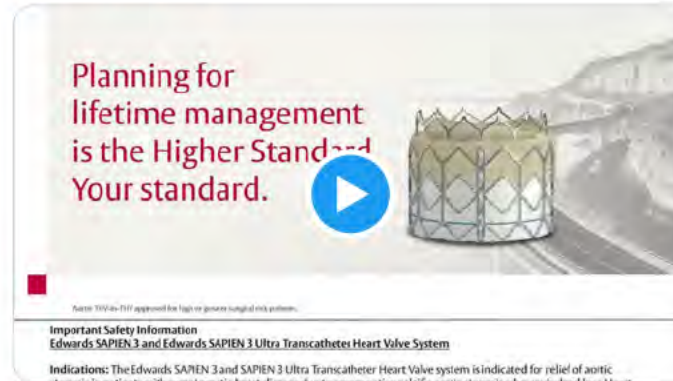
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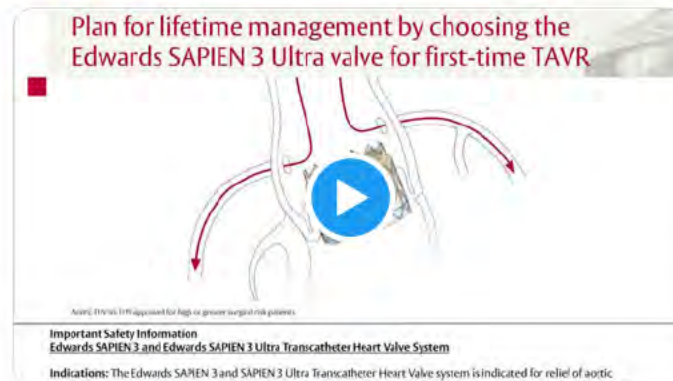
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EXHIBIT 70

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AORTIC INNOVATIONS LLC,)
)
Plaintiff,)
)
v.) C.A. No. 21-1377 (JPM)
)
EDWARDS LIFESCIENCES CORPORATION,)
EDWARDS LIFESCIENCES LLC and)
EDWARDS LIFESCIENCES (U.S.) INC.,)
)
Defendants.)

**EDWARDS DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION TO
DE-DESIGNATE VALVE DEMONSTRATIVE AS ATTORNEYS EYES ONLY**

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I. INTRODUCTION

Edwards properly designated its SAPIEN 3 Ultra demonstrative valve as Attorney’s Eyes Only. As explained in the Declaration of YJ Oh, Edwards’ Senior Vice President of Global and U.S. Marketing for Transcatheter Heart Valves, Edwards’ SAPIEN 3 Ultra demonstrative valve reflects highly sensitive technical information not apparent from photographs or videos. If it did not, Aortic would not be moving for its CEO to gain access to it. Moreover, Edwards protects the detailed technical information reflected in its demonstrative valve by not selling or giving it away to anyone. With respect to its commercial valves, Edwards sells those only to approved hospitals under agreements with confidentiality protections and restrictions on use. It does not sell its commercial valves to the general public, and certainly not to individuals or entities seeking to study the valves for the purpose of drafting patent claims to assert against Edwards.

Here, Aortic openly admits that it seeks to de-designate the demonstrative valve for an improper purpose—to use the valve to bolster its arguments in proceedings before the Patent Office. But Aortic never sought discovery of the valve during the IPR proceedings—where the Patent Office could have addressed any relevancy objections and the proper protections accorded to Edwards’ sensitive technical information in those proceedings. Here, the Stipulated Protective Order precludes parties from using information designated Confidential or AEO for any purpose other than *for this litigation*. Before providing the demonstrative valve to Aortic, Edwards confirmed that Aortic would treat it as AEO, limit its use to this litigation, and not use the valve for patent prosecution. To allow Aortic to use the valve for any other purpose would cause significant harm to Edwards, including giving Aortic the opportunity to reverse engineer the valve to discern details about the valve not generally known. Aortic would admittedly use that information against Edwards at the Patent Office. Moreover, throughout this litigation, Aortic has

grown its patent portfolio by attempting to tailor its patent claims to Edwards' SAPIEN 3 Ultra valve. This forces Edwards to incur additional and unnecessary defense costs, thereby affecting Edwards' profits and ability to innovate in the future.

Moreover, Aortic does not need for its CEO, Ali Shahriari, to have access to the valve to litigate this action. Aortic claims that Dr. Shahriari needs access to confirm its "authenticity." Mot. at 14. But Dr. Shahriari is not a practicing cardiac surgeon. His medical license lapsed years ago. He has never implanted a SAPIEN 3 Ultra valve and has no special knowledge or expertise regarding that valve to offer. Moreover, Aortic's technical expert, Stephen Brecker, M.D., is an interventional cardiologist who has implanted SAPIEN 3 Ultra. Under the Protective Order, Dr. Brecker has the ability to obtain access to the valve and assist Aortic's attorneys with any type of "authenticity" analysis they would like to do, provided it is for purposes of this litigation.

II. BACKGROUND

A. Edwards SAPIEN 3 Ultra THV System

In November and December 2018, Edwards received regulatory approval to sell its SAPIEN 3 Ultra transcatheter heart valve (THV) System in Europe and the United States, respectively. Oh Decl. ¶2. All of its sales are governed by the approvals granted by the respective agency. *Id.*

Pursuant to a Consignment Agreement, Edwards consigns the SAPIEN 3 Ultra THV system to hospitals in a kit that includes the prosthetic heart valve, a delivery system, a crimper, and other accessories. Oh Decl. ¶¶3-5, 7. The valve is not visible to hospital staff when in the kit because the SAPIEN 3 Ultra valve is stored in a box with a tamper resistant seal and an identifying bar code. *Id.* Within that sealed box, the valve is stored in a jar of glutaraldehyde with a tamper

resistant seal. *Id.* That jar is covered in white labels, including an identifying bar code. It is not possible to see the valve details through the labels and the glutaraldehyde. *Id.*

The reason Edwards stores the SAPIEN 3 Ultra valve in glutaraldehyde is because the valve tissue consists of bovine pericardium tissue. *Id.* ¶9. Bovine pericardium tissue will degrade if stored in dry, open-air environments, so the valve is stored in a glutaraldehyde solution to preserve the bovine pericardium tissue. *Id.* Glutaraldehyde is a hazardous chemical that is likely to irritate the eyes and skin of a person who comes into contact with it. *Id.* Therefore, Edwards advises that anyone handling the SAPIEN 3 Ultra device wear protective equipment, such as gloves, a lab coat, a face shield, and goggles. *Id.*

Once the implanting team removes the SAPIEN 3 Ultra valve from the glutaraldehyde, they rinse it in two different bowls of saline for 1 minute each. *Id.* ¶10. After it is rinsed in saline, the valve is crimped onto the delivery system and must be implanted in the patient within 30 minutes. *Id.*

In September 2022, Edwards launched its SAPIEN 3 Ultra valve with RESILIA tissue following FDA approval. *Id.* ¶11. The RESILIA tissue is bovine pericardial tissue treated with advanced anti-calcification technology. *Id.* The SAPIEN 3 Ultra RESILIA valve is packaged in a sterile plastic container within a sealed foil pouch and is not visible through the foil pouch. *Id.* Both the foil pouch and the plastic container include bar codes that identify the valve for tracking purposes. *Id.* Edwards also consigns the SAPIEN 3 Ultra RESILIA THV System to hospitals pursuant to the same Consignment Agreement as the original Ultra system. *Id.*

Edwards' Consignment Agreement requires each hospital to use the SAPIEN 3 Ultra THV system "only for its own internal use" (Oh Decl. Ex. 1, ¶1) and "only for immediate use in

providing care to Consignee’s patients.” (*Id.* ¶6). It also provides that purchases of Consigned Products are governed by the “terms and conditions set forth in the Pricing Agreement.” (*Id.* ¶2).

B. Edwards Sells Its SAPIEN 3 Ultra THV System to Approved Hospitals Subject to Confidentiality Restrictions

Edwards sells its SAPIEN 3 Ultra THV system, including the original and RESILIA, only to approved hospitals with the facilities and personnel capable of implanting the valve in patients. Oh Decl. ¶¶3, 11. It does not sell its SAPIEN 3 Ultra THV System to any individual or entity other than an approved hospital. *Id.* Edwards sells its SAPIEN 3 Ultra system for tens of thousands of dollars pursuant to a Pricing Agreement with each hospital. *Id.* ¶¶6, 8. That Pricing Agreement requires hospitals maintain the confidentiality of Edwards’ information, including the details of its products:

Each party agrees that *all information provided to it* by the other party pursuant to this Agreement, *including information concerning pricing, products and customers, is confidential* and proprietary information of the disclosing party. Each party agrees not to disclose such confidential information directly or indirectly to any third party or to use such confidential information for any purpose other than for fulfilling its obligations under this Agreement. Upon either party's request, the other party shall return all confidential information to the requesting party or destroy all such information and certify in writing as to its destruction. This provision shall survive the termination or expiration of this Agreement.

Id., Ex. 2, ¶9 (emphases added).

C. Edwards’ Production of a Demonstrative SAPIEN 3 Ultra Valve

On March 10, 2022, this Court held a technology tutorial during which it requested that Edwards provide the Court with a sample SAPIEN 3 Ultra valve. D.I. 23 at 35 (recognizing that “mechanical engineers understand that it’s nice to actually have something tangible sometimes to get the proportions exactly right”). Edwards agreed to provide a sample valve, but because Edwards’ SAPIEN 3 Ultra valve is stored in glutaraldehyde to preserve the tissue leaflets, Edwards suggested that it provide a sample that has been modified to replace the bovine pericardium tissue

with a latex material for ease of handling the product. *Id.* at 83. Shortly thereafter, Edwards produced a demonstrative SAPIEN 3 Ultra valve to the Court.

Although Aortic had not served any discovery requests for the valve, Edwards agreed to produce the demonstrative SAPIEN 3 Ultra valve to Aortic provided Aortic agreed to (1) treat the valve as Attorney’s Eyes Only information, (2) use the valve only for purposes of this litigation, and (3) not use the valve for any patent prosecution activities. Mot. Ex. A. Aortic agreed. *Id.* Aortic now seeks to renege on that agreement and provide the valve to its CEO and founder, Ali Shahriari, to allegedly “authenticate” the valve and to use it in proceedings before the Patent Office.

III. LEGAL STANDARD

A party seeking to maintain the confidentiality of information need only demonstrate good cause. *Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1122 (3d Cir. 1986). “Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994). To determine whether good cause exists, courts balance a party’s need for information against the harm that might result from disclosure. *Id.* at 787. Factors that may be considered in evaluating whether good cause exists include:

(1) whether disclosure will violate any privacy interests; (2) whether the information is being sought for a legitimate purpose or for an improper purpose; (3) whether disclosure of the information will cause a party embarrassment; (4) whether confidentiality is being sought over information important to public health and safety; (5) whether the sharing of information among litigants will promote fairness and efficiency; (6) whether a party benefitting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public.

Glenmede Tr. Co. v. Thompson, 56 F.3d 476, 483 (3d Cir. 1995).

IV. ARGUMENT

A. Edwards Properly Designated Its SAPIEN 3 Ultra Demonstrative Valve

Edwards properly designated its SAPIEN 3 Ultra demonstrative valve as AEO under the stipulated Protective Order, which provides that a party may designate as ATTORNEYS EYES ONLY “highly sensitive business . . . information, the disclosure of which is likely to cause significant harm . . . to the business or competitive position of the designating party.” D.I. 47 ¶4. Disclosure to Dr. Shahriari would violate Edwards’ privacy interests in its highly sensitive information reflected in the demonstrative valve. *See Glenmede*, 56 F.3d at 483 (factors considered in evaluating whether good cause exists include whether disclosure would violate any privacy interests).

Edwards’ SAPIEN 3 Ultra demonstrative valve contains highly sensitive technical information proprietary to Edwards. Oh Decl. ¶¶16-17. The valve reflects the same overall appearance and component materials (skirts, frame, sutures) as the commercial SAPIEN 3 Ultra valve, but is more easily handled and studied because it is not stored in a hazardous chemical. *Id.* ¶¶12, 16-17. Highly sensitive design details present in the physical valve include precisely how and where the leaflets and the skirts are attached to the valve including, how and where the leaflet connections are formed, how and where sutures are placed, and how and where the skirts and leaflets are folded. *Id.* ¶ 16. These intricate design details cannot be discerned from publicly available photographs or a video. *Id.* Many of them would require disassembly of the physical valve to discern. *Id.* For example, having the physical valve would allow a third party to determine the exact knitting/weaving patterns for the skirts, which are proprietary information of Edwards. *Id.* These intricate design details contribute to the SAPIEN 3 Ultra valve’s advantages, making it the leading THV valve on the market. *Id.*

The information reflected in Edwards' SAPIEN 3 Ultra demonstrative valve is not generally available to the public. Thus, Edwards has a privacy interest in protecting those features from disclosure to competitors and others. *Gerwitz v. Corizon Health, Inc.*, No. 2:19-CV-06191-KSM, 2020 WL 12688363, at *2 (E.D. Pa. Nov. 23, 2020) (finding a privacy interest in trade secrets and confidential commercial information). As described in the Background Section, Edwards does not sell or distribute its SAPIEN 3 Ultra demonstrative to anyone outside of Edwards. Oh Decl. ¶14. It sells its commercial valve only to approved hospitals subject to both contractual and practical confidentiality and use restrictions. *Id.* ¶¶3-6. All approved hospitals sign a Pricing Agreement and a Consignment Agreement that includes a duty to maintain the confidentiality of the valve and to use it “only for immediate use in providing care to [its] patients.” *Id.*, Ex. 2, ¶9, Ex. 1, ¶6; see *Syncsort Inc. v. Innovative Routines, Int’l, Inc.*, No. 04-3623 (WHW), 2011 WL 3651331, *15 (D.N.J. Aug. 18, 2011) (trade secrets are not negated by distribution if appropriate measures are taken to protect the information including confidentiality agreements). The valves are stored in packaging that prevents others from seeing the valve. Oh Decl. ¶7. Edwards' personnel closely monitor the hospital's use of the valves, which are an expensive, consigned product. *Id.* ¶8. Thus, Aortic is incorrect when it repeatedly argues that the commercial valve is “publicly available to doctors and hospitals around the world” and “routinely handled by doctors without confidentiality protections.” Mot. at 6-7. The images and video clips cited by Aortic do not show otherwise or provide a reason not to maintain the AEO designation on the physical valve. See *Syncsort*, 2011 WL 3651331, *13 (publication on the Internet may not destroy a secret if it is “sufficiently obscure or transient or otherwise limited so that it does not become generally known to the relevant people”). As explained above, the physical valve can be disassembled to learn many proprietary details of the valve not discernable from an image or video

clip. Indeed, if the images and video clips reflected those details, then Aortic would not be moving for its CEO to gain access to the physical valve.

Aortic cites the *Avago* case to argue that “product samples in a litigation should not be given greater confidentiality treatment than they are given outside of the litigation.” Mot. at 6 (citing Ex. C, *Avago Tech. Fiber IP v. IPTRONICS, Inc.*, C 10-CV-02863 EJD (PSG), D.I. 349 at 2-3 (N.D. Cal. Jan. 2, 2013)). But that case applied the “least restrictive means” test, i.e., whether a protective designation limited disclosure more than necessary or essential to protect the interests furthered by Rule 26(c). *See Avago*, D.I. 349 at 2. The Third Circuit previously rejected that test, holding that “[t]he good cause standard is significantly less demanding than the least restrictive means test.” *Cipollone*, 785 F.2d at 1120. Aortic fails to acknowledge this, despite also having cited the *Cipollone* case. *See* Mot. at 5-6. Here, Edwards sells the commercial valve subject to a contractual obligation that the hospitals maintain the valve’s confidentiality and use it only for its intended purpose in patients. As such, Edwards’ commercial valve is not publicly available and, as explained herein, Edwards would be harmed by its disclosure to Aortic’s CEO.

Thus, good cause exists to maintain the AEO designation on the SAPIEN 3 Ultra valve demonstrative, which reflects highly sensitive technical information not generally known to the public. *See Tech Pharmacy Servs., LLC v. Alixa Rx LLC*, No. 4:15-CV-766, 2017 WL 3475440, *2 (E.D. Tex. Aug. 11, 2017) (denying motion to remove confidentiality designation where the moving party offered no evidence of disclosure of the disputed documents to parties other than customers).

B. Aortic Is Not Unfairly Prejudiced by the AEO Designation

1. Aortic’s CEO Has No Legitimate Need for Access to the Valve but Disclosure to Him Would Harm Edwards

Aortic offers two reasons regarding its need for the demonstrative. Both lack merit. First, Aortic contends that Dr. Shahriari has been kept “in the dark about the nature and authenticity of the demonstrative.” Mot. at 14. But Aortic has no basis to question its authenticity. Even if it did, Aortic has not provided any evidence that Dr. Shahriari has ever handled or implanted a SAPIEN 3 Ultra valve such that he would be able to authenticate the demonstrative. Dr. Shahriari is not a practicing cardiac surgeon. His medical license lapsed almost 4 years ago, which was around the time that Edwards launched the Sapien 3 Ultra THV system. Lea Decl. Ex. 3. Rather, Dr. Shahriari is the founder and CEO of Aortic Innovations, a company that does not make or sell a product. Aortic is a holding company for Dr. Shahriari’s patent portfolio on TAVR devices. Dr. Shahriari is an experienced businessman having previously founded another medical device company called Ascyrus Medical in 2015, which he sold to CryoLife in 2020 for up to \$200 million, including \$60 million upfront cash. *Id.* Ex. 10.

Moreover, Aortic has a technical expert, Dr. Brecker, who is a practicing interventional cardiologist with experience implanting SAPIEN 3 Ultra products. Dr. Brecker has also served two declarations in support of Aortic’s claim construction positions. As an expert retained by a party to assist in this action, Dr. Brecker could have full access to the demonstrative under the Stipulated Protective Order, provided he completes the required Acknowledgement. D.I. 47 at 6. Yet, Aortic’s attorneys, who assertedly need help authenticating the valve, have never served on Edwards a signed Acknowledgement by Dr. Brecker. Moreover, Aortic’s attorneys, who also have access to the demonstrative, will have ample opportunity to take discovery regarding the

demonstrative's "authenticity." For example, they could notice a deposition of Edwards. Thus, there is no legitimate reason that Dr. Shahriari must have access to the demonstrative to "authenticate" it, or any indication that he would be qualified to do so.

Aortic complains that the parties' agreed-upon Stipulated Protective Order allows for disclosure of AEO information only to in-house counsel and not employees, which Aortic claims disadvantages Aortic because it lacks in-house counsel. Mot. at 13. But the Stipulated Protective Order allows access to AEO information only by in-house counsel *who are not involved in competitive decision making*. D.I. 47, at 5. Dr. Shahriari is clearly involved in competitive decision making and would not qualify to access AEO information regardless of whether he was in-house counsel. Under Aortic's logic, Aortic's lack of in-house counsel would entitle Dr. Shahriari, a competitive decision maker, to access *all* of Edwards' confidential attorneys-eyes-only information produced in this case, despite his role in competitive decision making, completely nullifying the protections in the Stipulated Protective Order to which Aortic previously agreed.

Second, Aortic argues that it needs the demonstrative to defend itself in the IPRs of its asserted patents. Mot. at 14-15. This argument is both legally and factually flawed for several reasons. First, Edwards produced the demonstrative in this litigation at the Court's request to aid the Court in understanding the technology. *See* D.I. 23 at 35-36, 83. Aortic's alleged need to use the demonstrative in the IPRs is not related to this action and is not a proper use of the demonstrative. If Aortic truly needed the SAPIEN 3 Ultra demonstrative to respond to any arguments in the IPRs (it does not), Federal Regulations and PTAB rules expressly allow for Aortic to seek such discovery in the IPRs. *See* 37 C.F.R. §§42.51(b), 42.52(a); *see also* Lea Decl. Ex. 4 (Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019) at 22-34. Aortic has not availed itself of any of those procedures, thereby denying Edwards the ability to