2020 Investor Conference

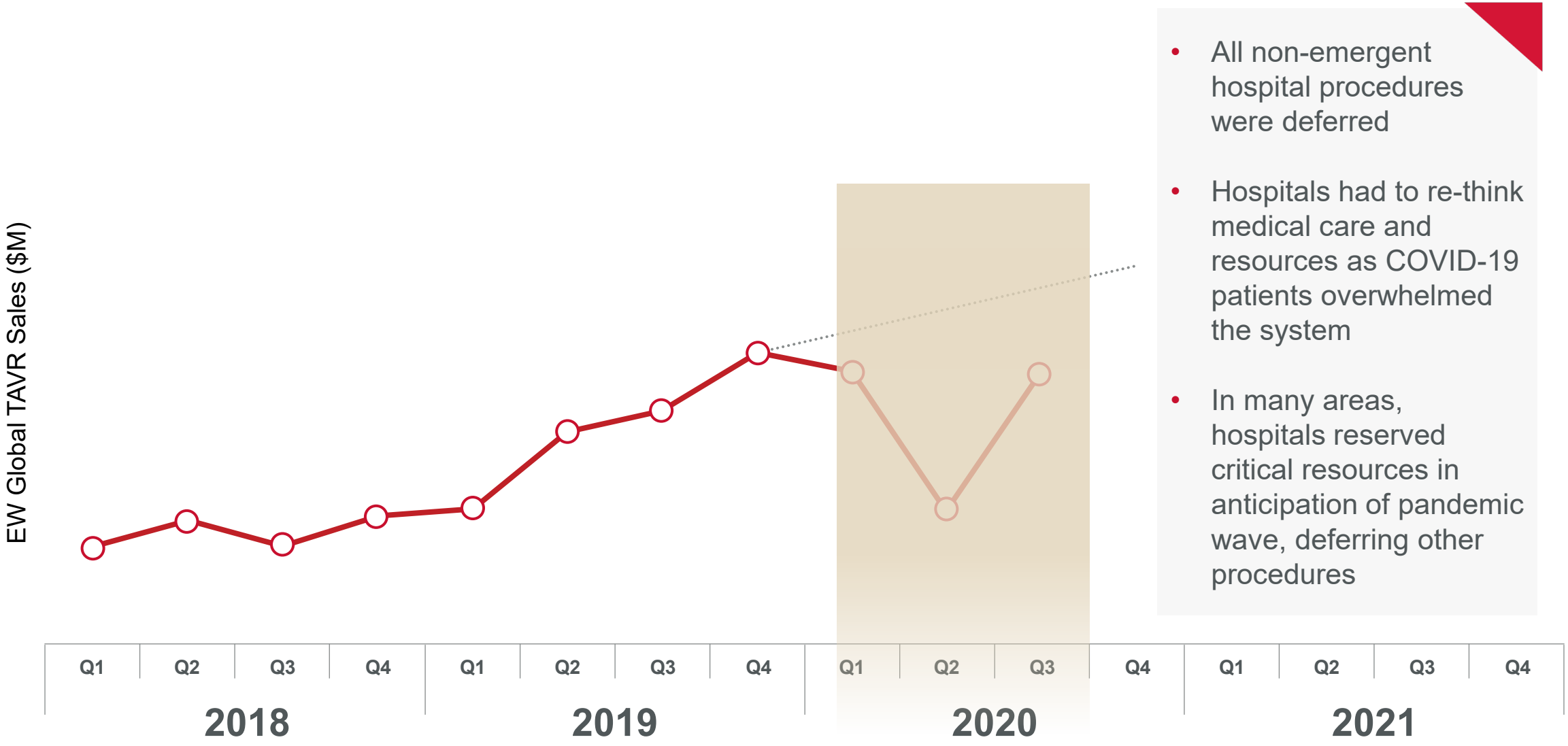
Transcatheter Aortic Heart Valves

Edwards

We entered 2020 with strong momentum on a path to exceed our goals…

- PARTNER 3 results demonstrated SAPIEN 3 is the only valve superior to surgery
- Low-risk approval in U.S. and EU
- In U.S., revised NCD drove therapy access
- Strong trajectory in the first 10 weeks of 2020

…then the pandemic hit



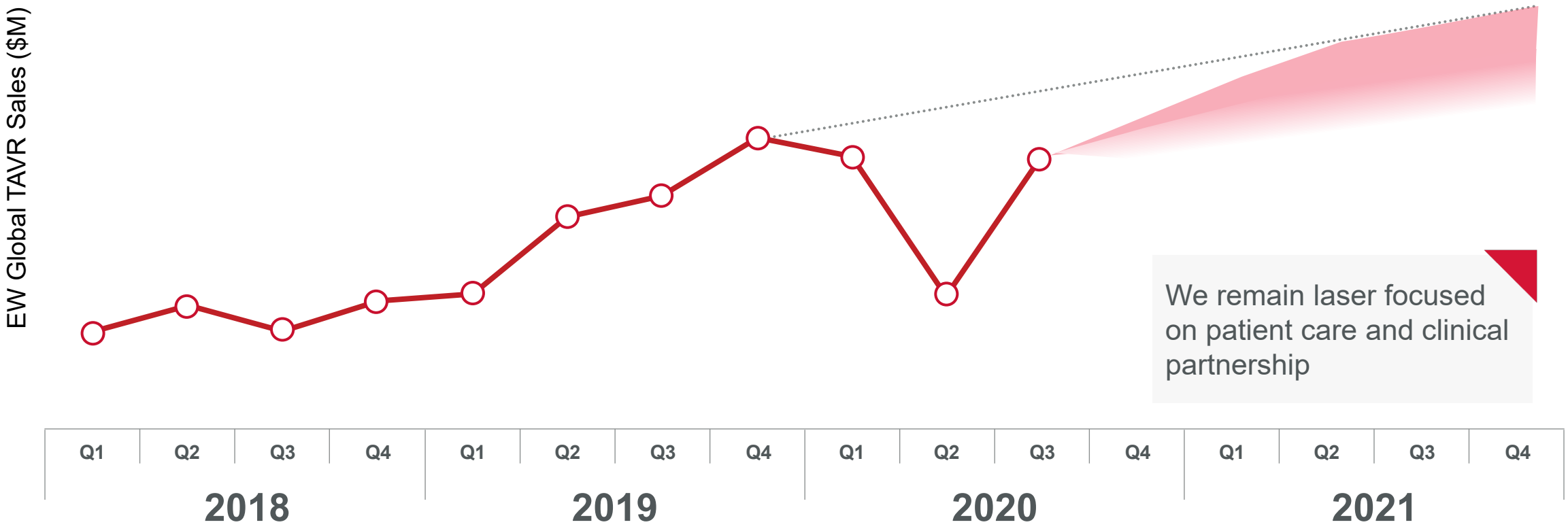
- All non-emergent hospital procedures were deferred
- Hospitals had to re-think medical care and resources as COVID-19 patients overwhelmed the system
- In many areas, hospitals reserved critical resources in anticipation of pandemic wave, deferring other procedures

But we did not stop…

Severe Aortic Stenosis is a deadly disease

Severe AS patients' mortality rates increase drastically as patients wait for treatment

Helping patients remains our top priority



We remain laser focused on patient care and clinical partnership

Edwards data on file; 2020 Q4 and 2021 internal range estimates. Forecast is an illustration and not to scale.

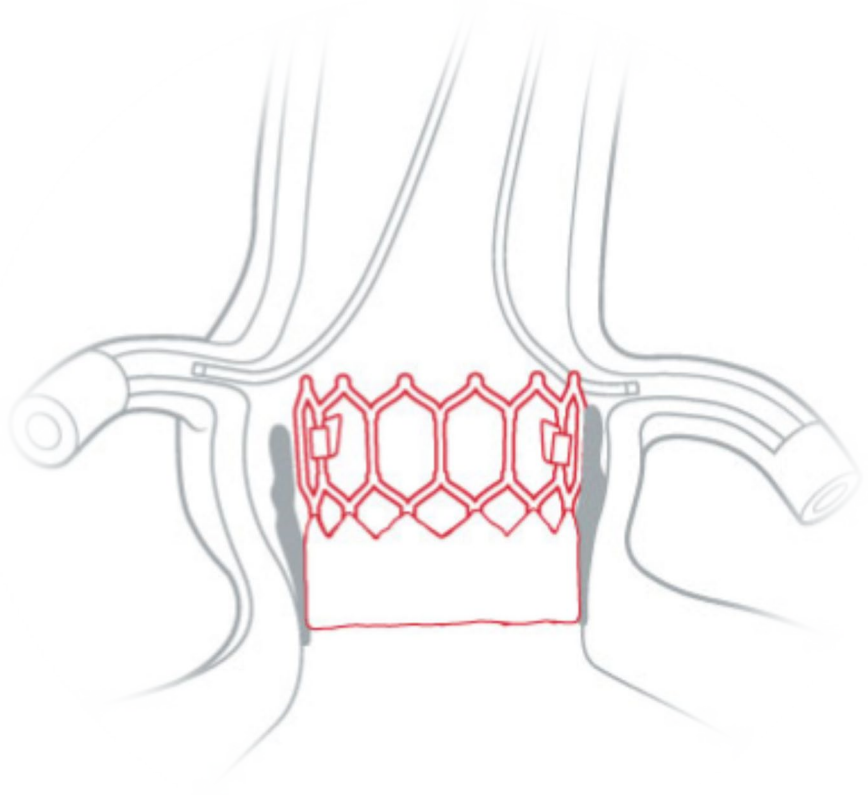
Bicuspid precaution removed

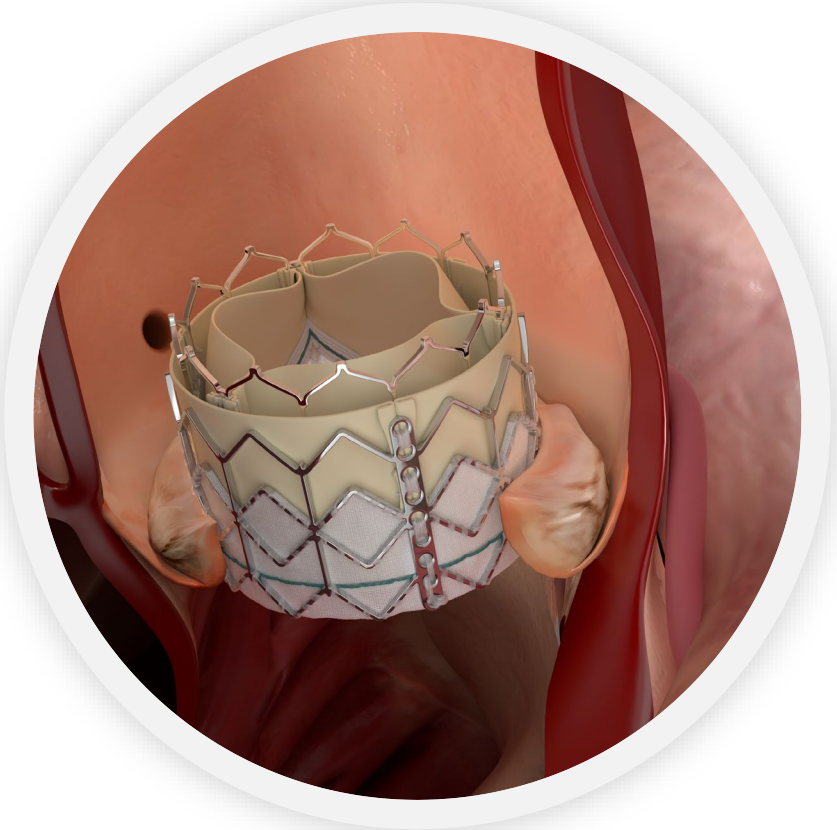
Provides further confidence for low risk, younger patients

Low rates of complications that matter most to bicuspid patients[1]		
CEC-adjudicated Event	30 Days (n=71)	1 Year (n=71)
All-cause mortality	0%	1.4%
All stroke	2.8%	2.8%
Disabling stroke	0%	0%
New permanent pacemaker	9.9%	11.3%
Moderate/severe PVL	1.4%	0%

1. PARTNER 3 bicuspid nested registry analysis
2. FDA precaution removal letter dated 22nd July 2020

Edwards SAPIEN 3 TAVR Now Approved for TAVR-in-TAVR Indication





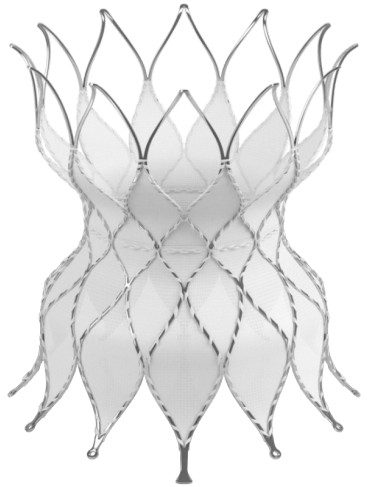
Provides long-term treatment option for patients with AS and reflects our dedication to long-term care

Expanding Options for Congenital Pulmonic Heart Disease Patients

- SAPIEN 3 now approved for pulmonic patients (direct valve replacement)
- Alterra Adaptive Prestent and SAPIEN 3 Pulmonic System expands therapy
- Alterra U.S. Approval anticipated in 2H 2021

SAPIEN 3 Valve

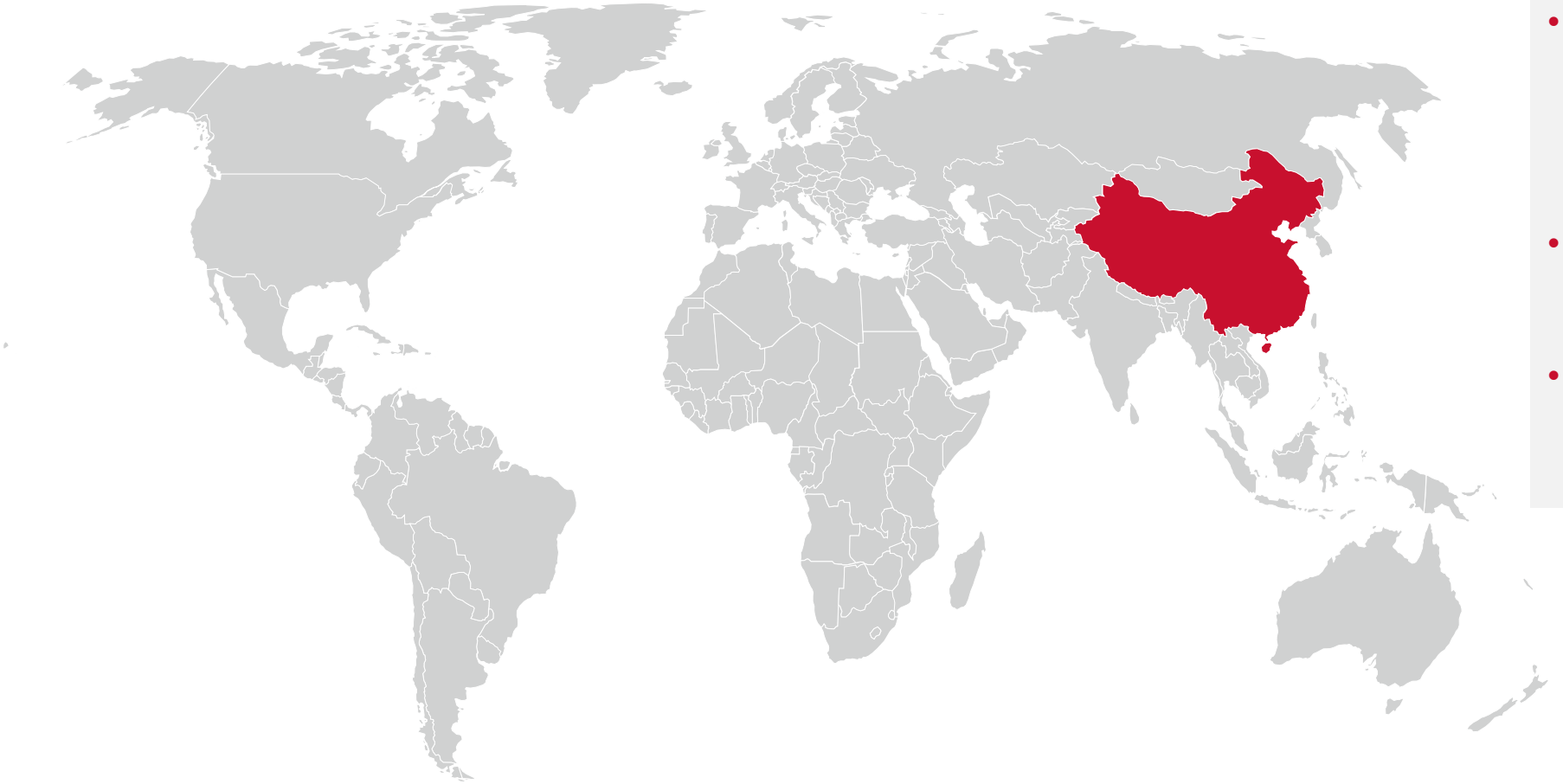
+



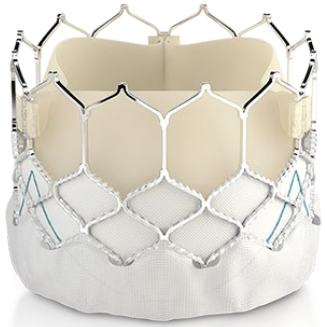
Alterra Adaptive Prestent

Congenital Pulmonary Valve disease is a serious issue, and these patients have unique challenges

SAPIEN 3 Now Approved in China For High Risk Patients



- Focused on establishing strong relationships to become the trusted clinical partner
- Patient outcomes remain the priority
- Contributor to long-term growth



The COVID-19 experience helped to inform our future

- Patients with Aortic Stenosis don't wait well, and TAVR is an essential procedure
- High-touch model remains valued
- We expect hospitals to adapt to local outbreaks and prioritize structural heart procedures until the pandemic subsides
- TAVR outcomes and efficiencies will continue to be highly valued

Data from New York City and Switzerland demonstrate risks of waiting

In the first study from New York City, 10% of patients awaiting aortic valve replacement at a busy structural heart program ended up undergoing urgent TAVR or died during in the first 30 days after elective procedures were halted. By 3 months, more than one-third of patients affected by the ban on elective procedures required an urgent intervention or died, the vast majority sent for TAVR because of worsening symptoms.

Across the pond, Swiss researchers reported that nearly one in five patients scheduled for aortic valve replacement who had the procedure delayed reported to hospital with valve-related symptoms or worsening heart failure. Thomas Pilgrim, MD (Bern University Hospital), senior researcher of the prospective Aortic Stenosis Defer (AS-DEFER) study, said elective procedures were halted in Switzerland on March 20, 2020, but they knew they'd have to take on selected patients given their risk.

"TAVR Delays During Pandemic's Peak Led to Hospitalizations, Deaths", www.tctmd.com, Sept 30, 2020

PARTNER 3 Best-in-Class Outcomes

99%
Freedom from death and disabling stroke at 1 year

96%
of patients discharged home

90%
did not need to be rehospitalized within 2 years

Low pacemaker rates

Low rates of PVL

PVL: Paravalvular Leak

Edwards' TAVR allows hospitals to treat patients with confidence

Low complication rates

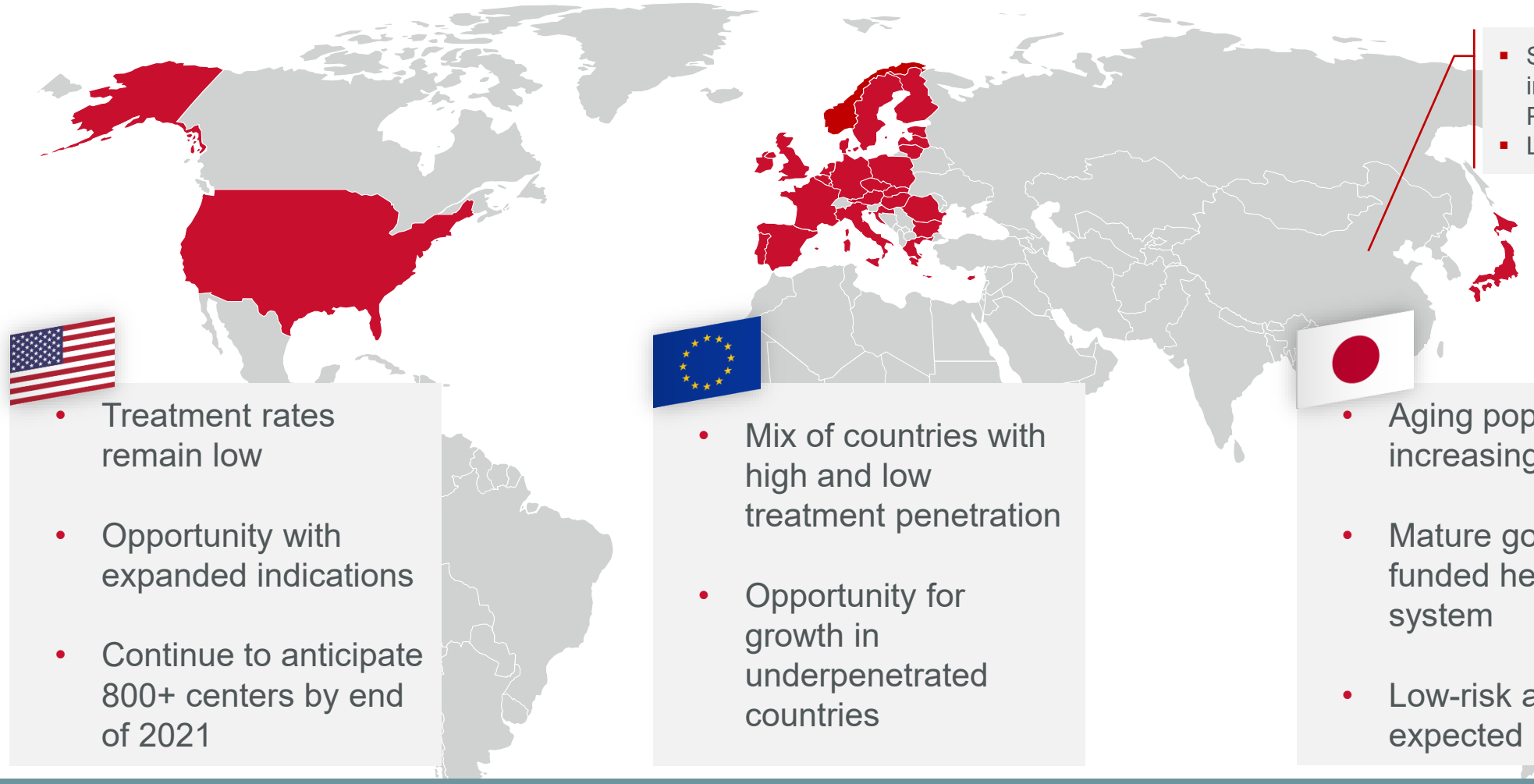
Short length-of-stay

Patients discharged home

Low re-hospitalization rates

TAVR has become a healthcare priority and Edwards' TAVR advantage is now stronger than ever

TAVR fundamentals remain strong in developed markets around the world



- SAPIEN 3 now approved in China For High-Risk Patients
- Long-term opportunity

- Treatment rates remain low
- Opportunity with expanded indications
- Continue to anticipate 800+ centers by end of 2021

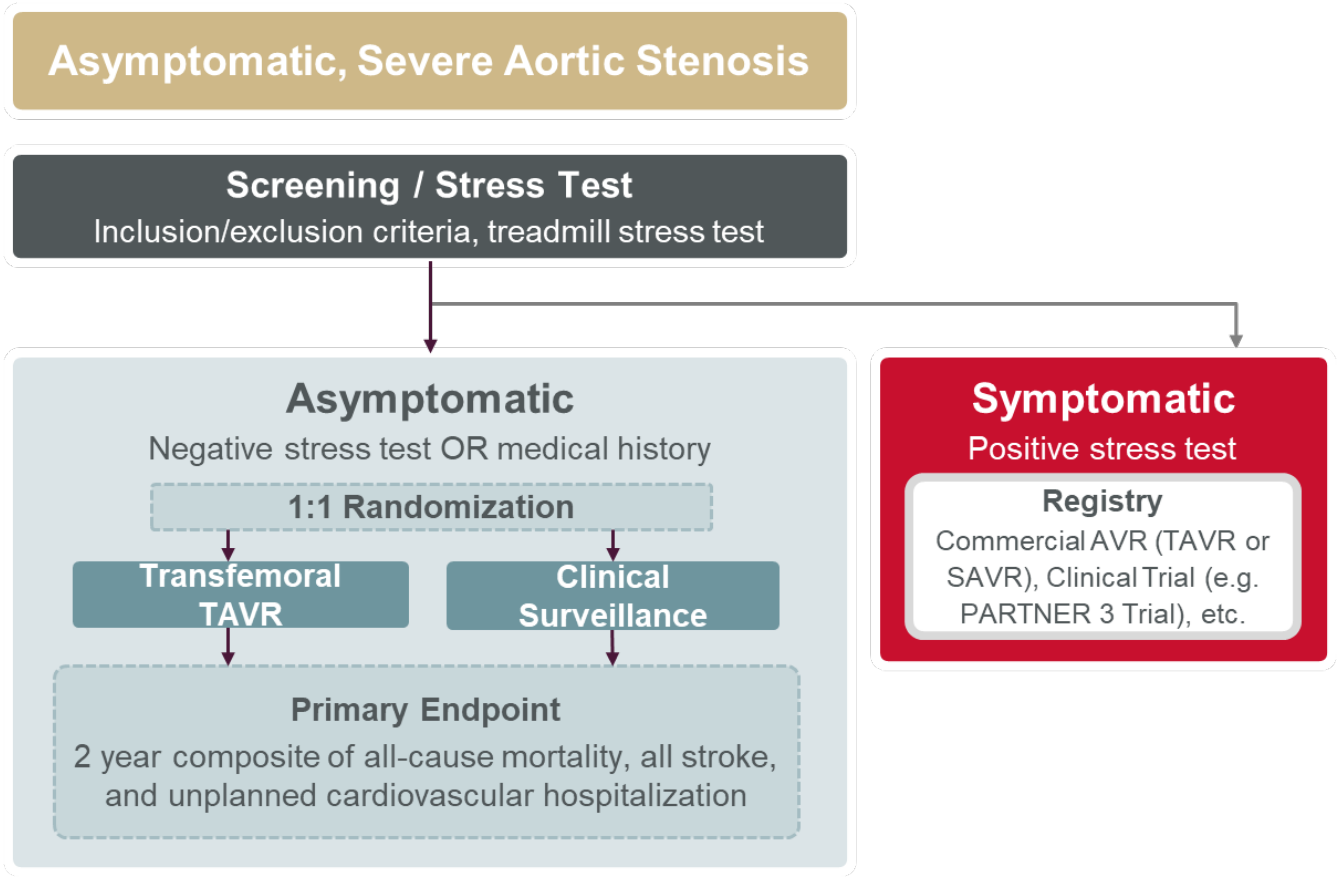
- Mix of countries with high and low treatment penetration
- Opportunity for growth in underpenetrated countries

- Aging population increasing rapidly
- Mature government-funded healthcare system
- Low-risk approval expected in 2021

We Continue to Expect the Global TAVR Market Opportunity to Exceed $7B by 2024

Asymptomatic and Moderate Risk Clinical Trials

Expected to add significant growth beyond 2024

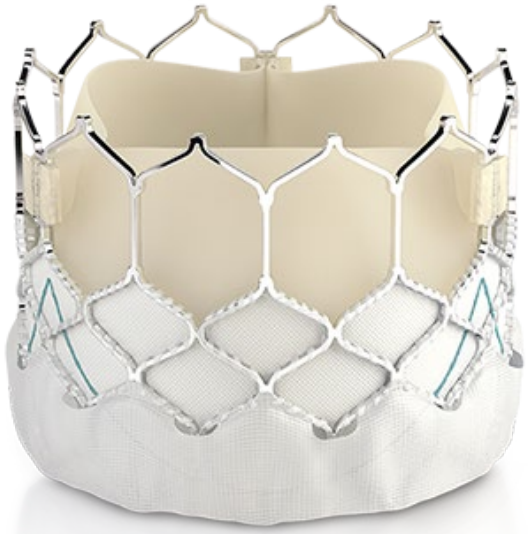


- Beyond Severe Aortic stenosis, we believe our TAVR therapy may benefit patients with Moderate Aortic Stenosis
- Currently working closely with KOLs on a pivotal trial design

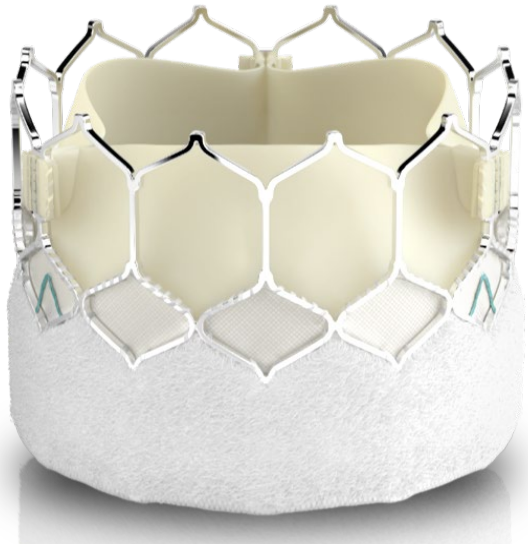
Anticipate completion of EARLY TAVR enrollment in 2021

Anticipate FDA approval to start the Moderate AS trial in 2021

Our portfolio is constantly evolving



SAPIEN 3



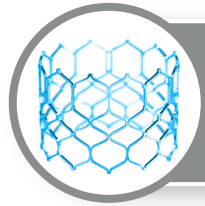
SAPIEN 3 Ultra

U.S. and EU launches evolutionary advancements

Next-Generation

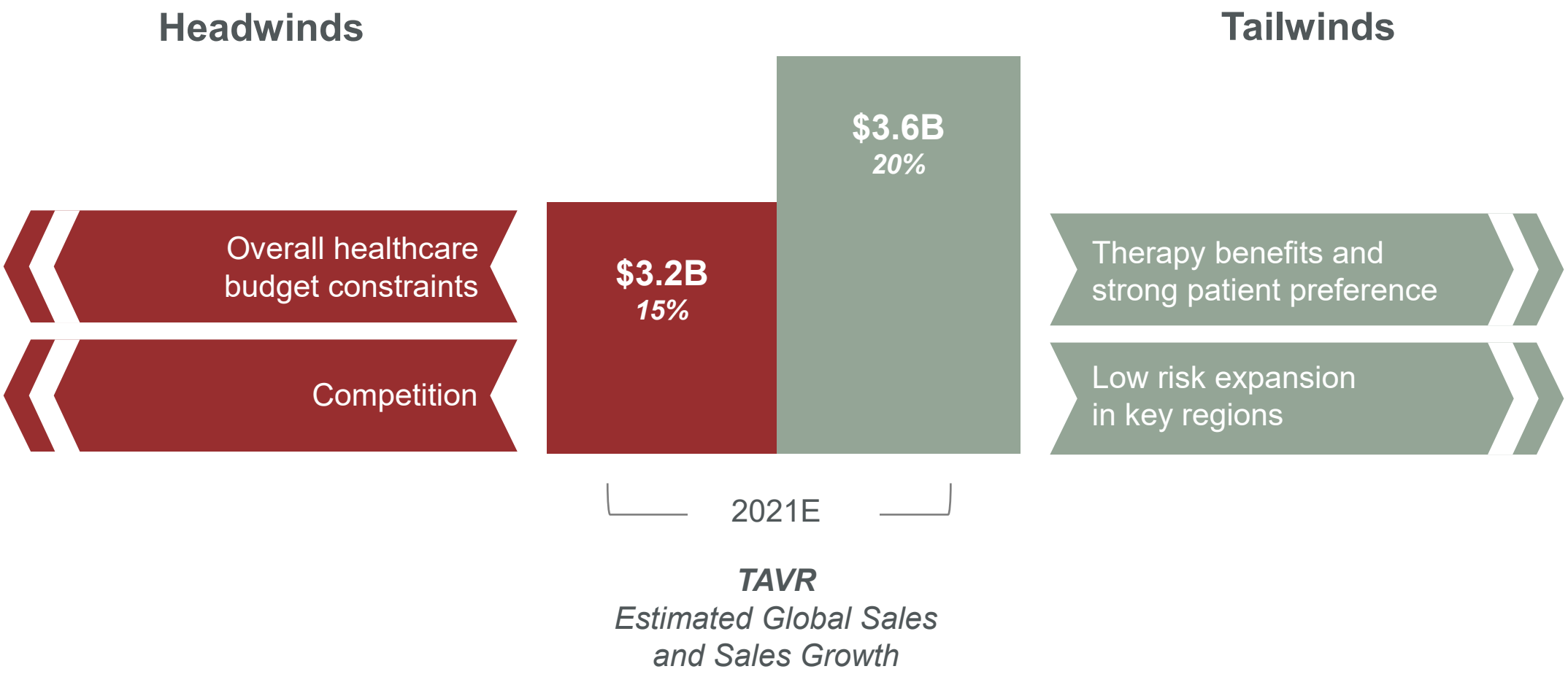
SAPIEN X4

Clinical work expected to begin in U.S. in 2021



Revolutionary platform

2021 Global Sales Outlook



Executive Summary

- **Aortic Stenosis is a deadly disease** and timely treatment is paramount
- Globally, **diagnosis and treatment rates of AS remain low** providing opportunity for low-double digit TAVR growth long-term
- We have **learned from the pandemic** and Edwards' TAVR therapy **fundamentals remain strong**
- Continued **investment in groundbreaking trials** beyond severe symptomatic aortic stenosis and transformational technologies to treat patients

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

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 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 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the 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.

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. 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 bioprostheses 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, 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 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, 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. Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, and lead to patient death or serious injuries associated with difficulty retrieving the delivery system and surgical intervention.

Precautions: Safety, effectiveness, and durability have not been established for THV-in-THV procedures. 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. 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 or abnormalities in the atrial septum preventing safe transseptal access. Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation 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 any 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; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture); 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. Ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor PA pressure in homolateral radial artery. Residual mean gradient may be higher in a “THV-in-failing bioprosthesis” 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 bioprosthetic valve 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 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 Axela Sheath

Indications: The Edwards Axela sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Ultra delivery system.

Contraindications: There are no known contraindications.

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.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29 mm Edwards SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 Ultra transcatheter heart valve and the Edwards SAPIEN 3 transcatheter heart valve for implantation. Contraindications: There are no known contraindications. 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. Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use. Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

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

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

Edwards

Helping Patients is Our Life's Work, and *life is now*