

#### **FOR IMMEDIATE RELEASE**

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#### **EDWARDS LIFESCIENCES REPORTS FIRST QUARTER RESULTS**

IRVINE, Calif., April 20, 2021 — Edwards Lifesciences (NYSE: EW) today reported financial results for the quarter ended March 31, 2021.

## First Quarter Highlights and 2021 Outlook

- Sales grew 8 percent to \$1.2 billion; underlying 1 sales grew 5 percent
- TAVR sales grew 7 percent; underlying sales grew 4 percent
- EPS of \$0.54 exceeded expectations
- Received approval for a U.S. pivotal trial for TAVR in moderate AS patients
- Received TAVR approval in Japan for patients at low surgical risk
- First patients were treated with EVOQUE Eos transcatheter mitral replacement system
- Initiated TRISCEND II U.S. pivotal trial for transcatheter tricuspid replacement
- Completed Accelerated Share Repurchase
- Continued confidence in sales outlook; Adjusted EPS guidance of \$2.07 to \$2.27 increased \$0.07

"We recognize that there are many people still struggling with the pandemic around the world, yet as we anniversary the start of the pandemic, I'm encouraged by the signs of recovery," said Michael A. Mussallem, chairman and CEO. "Structural heart procedures increased as we progressed through the winter months, and our sales growth this quarter was better-than-expected. Although we anticipate the effects of the pandemic will impact structural heart patients in the near term, we have continued confidence in our positive 2021 outlook."

#### First Quarter 2021 Results

Sales for the quarter ended March 31, 2021 were \$1.2 billion, up 8 percent over the prior year, or 5 percent on an underlying basis. Diluted earnings per share for the quarter were \$0.54.

## <u>Transcatheter Aortic Valve Replacement (TAVR)</u>

For the quarter, the company reported global TAVR sales of \$792 million, a year-over-year increase of 7 percent on a reported basis and 4 percent on an underlying basis. The SAPIEN 3 Ultra platform continues to be differentiated with low complication rates, as well as ease-of-use, and significant potential for length-of-stay efficiency. Earlier this month, the company received approval to begin treating

patients at low surgical risk in Japan with SAPIEN 3 valves, and expects reimbursement approval later this year. Edwards also announced the company received approval for a U.S. pivotal trial for TAVR in moderate aortic stenosis (AS) patients, and expects enrollment to begin later this year.

The company continues to anticipate underlying sales growth in the 15 to 20 percent range in 2021, with continuing near-term COVID-related challenges turning to a more normalized environment in the second half of the year.

Edwards remains confident that the TAVR global opportunity will exceed \$7 billion by 2024, which implies a compounded annual growth rate in the low double digits.

## **Transcatheter Mitral and Tricuspid Therapies (TMTT)**

Edwards continued to enroll five pivotal trials across the company's differentiated portfolio of technologies to support patients suffering from tricuspid and mitral regurgitation.

The company progressed with the enrollment of three CLASP pivotal trials for the PASCAL platform and continues to expect approval for patients with degenerative mitral regurgitation late next year. This is expected to be the first commercial approval of the PASCAL system in the U.S. The company also began treating patients with the EVOQUE tricuspid valve replacement system in the TRISCEND II randomized pivotal study in accordance with the U.S. Food and Drug Administration's breakthrough pathway designation. In addition, Edwards announced the first patients were treated with EVOQUE Eos, the company's next-generation transcatheter mitral replacement system, through the MISCEND study.

First quarter global TMTT sales were \$16 million, driven by continued adoption of the company's PASCAL system and activation of more centers across Europe.

Edwards continues to estimate the global TMTT opportunity will reach \$3 billion by 2025 and remains committed to transforming the treatment of patients with mitral and tricuspid valve disease around the world.

## **Surgical Structural Heart and Critical Care**

Surgical Structural Heart sales for the quarter were \$213 million, up 10 percent compared to the first quarter of 2020, and up 7 percent on an underlying basis. The company remains encouraged by the steady global adoption of its premium products, which are bolstered by the five-year data from its COMMENCE clinical trial that has demonstrated the excellent durability of the RESILIA tissue technology. The quarter's results included increased adoption of the INSPIRIS RESILIA aortic surgical valve, which the company also began selling in China in the first quarter. Additionally, the MITRIS RESILIA mitral surgical valve is now being launched in Japan.

Critical Care sales were \$196 million for the quarter, representing an increase of 7 percent versus the first quarter of 2020, or 4 percent on an underlying basis. Growth was driven by increased sales of technologies for the both operating room and intensive care units. HemoSphere advanced monitoring platform orders increased as hospital capital spending began to show signs of recovery. Demand for the

company's products used in high-risk surgeries remained strong and the ClearSight non-invasive finger cuff in elective procedures recovered to near pre-COVID levels.

# **Additional Financial Results**

For the quarter, the company's adjusted gross margin was 76.0 percent, compared to 76.7 percent in the same period last year. This reduction was driven by a negative impact from FX and incremental costs associated with responding to COVID, partially offset by improved manufacturing efficiencies.

Selling, general and administrative expenses in the first quarter were \$331 million, or 27.2 percent of sales, compared to \$308 million in the prior year. This increase was primarily driven by the strengthening of foreign currencies, primarily the Euro, and personnel-related costs, partially offset by reduced travel spending resulting from COVID.

Research and development expenses in the first quarter were \$207 million, or 17.0 percent of sales, compared to \$187 million in the prior year. This increase was primarily the result of continued investments in the company's transcatheter innovations.

Free cash flow for the first quarter was \$195 million, defined as cash flow from operating activities of \$301 million, less capital spending of \$106 million.

Cash and investments totaled \$2.1 billion at March 31, 2021. Total debt was \$595 million. The company purchased 3.6 million shares for \$303 million during the first quarter. Repurchases were accomplished through an accelerated share repurchase program and a pre-established 10b5-1 program.

#### **Outlook**

Overall, full year 2021 sales guidance for Edwards remains at \$4.9 to \$5.3 billion. The company is raising full year 2021 adjusted earnings per share to \$2.07 to \$2.27 from \$2.00 to \$2.20.

For the second quarter of 2021, the company projects total sales to be between \$1.25 and \$1.33 billion, and adjusted EPS of \$0.54 to \$0.60.

"We remain confident in our long-term patient-focused strategy and our innovation pipeline. To serve the many patients suffering from structural heart disease, during the pandemic we have never stopped investing in our people, our innovative technologies and our new growth capacity," said Mussallem. "As a company, we expect that Edwards will be positioned even stronger and will be able to help more patients than ever as the world fully emerges from the pandemic."

### **About Edwards Lifesciences**

Edwards Lifesciences is the global leader of patient-focused innovations for structural heart disease and critical care monitoring. We are driven by a passion for patients, dedicated to improving and enhancing lives through partnerships with clinicians and stakeholders across the global healthcare landscape. For more information, visit Edwards.com and follow us on Facebook, Instagram, LinkedIn, Twitter and YouTube.

### **Conference Call and Webcast Information**

Edwards Lifesciences will be hosting a conference call today at 2:30 p.m. PT to discuss its first quarter results. To participate in the conference call, dial (877) 704-2848 or (201) 389-0893. For 72 hours following the call, an audio replay can be accessed by dialing (877) 660-6853 or (201) 612-7415 and using conference number 13717235. The call will also be available via live or archived webcast on the "Investor Relations" section of the Edwards web site at ir.edwards.com or www.edwards.com.

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements can sometimes be identified by the use of words such as "may," "will," "should," "anticipate," "believe," "plan," "project," "estimate," "potential," "predict," "early clinician feedback," "expect," "intend," "quidance," "outlook," "optimistic," "aspire," "confident" or other forms of these words or similar expressions and include, but are not limited to, statements made by Mr. Mussallem, second quarter and full year 2021 financial guidance, statements regarding the TAVR and TMTT opportunity, the compounded annual growth rate for TAVR, statements regarding transforming patient treatment for TMTT, approvals, clinical outcomes, adoption, and the information in the Outlook section. No inferences or assumptions should be made from statements of past performance, efforts, or results which may not be indicative of future performance or results. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain, difficult to predict, and may be outside of the company's control. The company's forward-looking statements speak only as of the date on which they are made and the company does not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If the company does update or correct one or more of these statements, investors and others should not conclude that the company will make additional updates or corrections.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Factors that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements include risk and uncertainties associated with COVID pandemic, clinical trial or commercial results or new product approvals and therapy adoption; unpredictability of product launches; competitive dynamics; changes to reimbursement for the company's products; the company's success in developing new products and avoiding manufacturing and quality issues; the impact of currency exchange rates; the timing or results of R&D and clinical trials; unanticipated actions by the U.S. Food and Drug Administration and other regulatory agencies; unexpected litigation impacts or expenses; and other risks detailed in the company's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2020 and the company's other filings with the SEC. These filings, along with important safety information about our products, may be found at edwards.com.

Edwards, Edwards Lifesciences, the stylized E logo, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, CLASP, CLEARSIGHT, EOS, EVOQUE, EVOQUE EOS, HemoSphere, INSPIRIS, MITRIS, MISCEND, PASCAL, SAPIEN, SAPIEN 3, SAPIEN 3 Ultra, and TRISCEND are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners. This statement is made on behalf of Edwards Lifesciences Corporation and its subsidiaries.

<sup>[1] &</sup>quot;Adjusted" amounts are non-GAAP items. Adjusted sales, or "underlying" growth rates, in this press release excludes foreign exchange fluctuations. Adjusted earnings per share is a non-GAAP item computed on a diluted basis and in this press release also excludes intellectual property litigation expenses, amortization of intangible assets, and fair value adjustments to contingent consideration liabilities arising from acquisitions. See the Non-GAAP Financial Information page and reconciliation tables below.

## EDWARDS LIFESCIENCES CORPORATION

# **Unaudited Consolidated Statements of Operations**

(in millions, except per share data)

		Three Months Ended March 31,			
	2021	2020			
Net sales	\$ 1,216.6	\$ 1,128.7			
Cost of sales	293.4	265.1			
Gross profit	923.2	863.6			
Selling, general, and administrative expenses	330.8	307.8			
Research and development expenses	207.0	187.4			
Intellectual property litigation expenses	6.4	12.5			
Change in fair value of contingent consideration liabilities	(4.5)	(2.2)			
Operating income	383.5	358.1			
Interest income, net	(0.3)	(4.5)			
Other income, net	(5.5)	(1.9)			
Income before provision for income taxes	389.3	364.5			
Provision for income taxes	51.1	53.9			
Net income	\$ 338.2	\$ 310.6			
Earnings per share: (A)					
Basic	\$ 0.54	\$ 0.50			
Diluted	\$ 0.54	\$ 0.49			
Weighted-average common shares outstanding: (A)					
Basic	623.2	624.6			
Diluted	631.3	635.1			
Operating statistics					
As a percentage of net sales:					
Gross profit	75.9	% 76.5 %			
Selling, general, and administrative expenses	27.2	% 27.3 %			
Research and development expenses	17.0	% 16.6 %			
Operating income	31.5	% 31.7 %			
Income before provision for income taxes	32.0	% 32.3 9			
Net income	27.8	% 27.5 %			
Effective tax rate	13.1	% 14.8 %			

Note: Numbers may not calculate due to rounding.

<sup>(</sup>A) All 2020 share and per share amounts were adjusted for the May 29, 2020 three-for-one stock split.

# EDWARDS LIFESCIENCES CORPORATION

**Unaudited Balance Sheets** 

(in millions)

		rch 31, 2021	<b>December 31, 2020</b>	
ASSETS				
Current assets				
Cash and cash equivalents	\$	1,174.2	\$ 1,18	3.2
Short-term investments		156.4	21	9.4
Accounts receivable, net		586.6	51	4.6
Other receivables		77.7	8	38.2
Inventories		767.9	80	2.3
Prepaid expenses		77.3	7	75.1
Other current assets		229.1	20	08.2
Total current assets		3,069.2	3,09	1.0
Long-term investments		802.2	80	1.6
Property, plant, and equipment, net		1,417.9	1,39	5.2
Operating lease right-of-use assets		88.5	9	94.2
Goodwill		1,170.8	1,17	3.2
Other intangible assets, net		330.3	33	31.4
Deferred income taxes		209.3	23	80.9
Other assets		125.5	11	9.6
Total assets	\$	7,213.7	\$ 7,23	7.1
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Accounts payable and accrued liabilities	\$	772.5	\$ 86	66.7
Operating lease liabilities		26.5	2	27.2
Total current liabilities		799.0	89	3.9
Long-term debt		595.2	59	95.0
Contingent consideration liabilities		181.6	18	86.1
Taxes payable		215.3	21	5.3
Operating lease liabilities		67.1	7	72.7
Uncertain tax positions		224.2	21	4.4
Litigation settlement accrual		222.1	23	3.0
Other liabilities		250.8	25	52.4
Stockholders' equity				
Common stock		637.5	63	86.4
Additional paid-in capital		1,496.8	1,43	8.1
Retained earnings		4,903.2	4,56	5.0
Accumulated other comprehensive loss		(172.4)	(16	51.1)
Treasury stock, at cost		(2,206.7)	(1,90	<b>14.</b> 1)
Total stockholders' equity		4,658.4	4,57	4.3
Total liabilities and stockholders' equity	<u>\$</u>	7,213.7	\$ 7,23	7.1

### EDWARDS LIFESCIENCES CORPORATION Non-GAAP Financial Information

To supplement the consolidated financial results prepared in accordance with Generally Accepted Accounting Principles ("GAAP"), the Company uses non-GAAP historical financial measures. Management makes adjustments to the GAAP measures for items (both charges and gains) that (a) do not reflect the core operational activities of the Company, (b) are commonly adjusted within the Company's industry to enhance comparability of the Company's financial results with those of its peer group, or (c) are inconsistent in amount or frequency between periods (albeit such items are monitored and controlled with equal diligence relative to core operations). The Company uses the term "adjusted sales" or "underlying growth rate" when referring to non-GAAP sales information, which excludes foreign exchange rate fluctuations. The Company uses the term "adjusted" to also exclude intellectual property litigation expenses, amortization of intangible assets, and fair value adjustments to contingent consideration liabilities arising from acquisitions.

Management uses non-GAAP financial measures internally for strategic decision making, forecasting future results, and evaluating current performance. These non-GAAP financial measures are used in addition to, and in conjunction with, results presented in accordance with GAAP and reflect an additional way of viewing aspects of the Company's operations by investors that, when viewed with its GAAP results, provide a more complete understanding of factors and trends affecting the Company's business and facilitate comparability to historical periods.

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

Fluctuations in exchange rates impact the comparative results and sales growth rates of the Company's underlying business. Management believes that excluding the impact of foreign exchange rate fluctuations from its sales growth provides investors a more useful comparison to historical financial results. The impact of foreign exchange rate fluctuations has been detailed in the "Reconciliation of Sales by Product Group and Region."

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

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

#### The items described below are adjustments to the GAAP financial results in the reconciliations that follow:

**Intellectual Property Litigation Expenses** - The Company incurred intellectual property litigation expenses of \$6.4 million and \$12.5 million in the first quarter of 2021 and 2020, respectively.

**Change in Fair Value of Contingent Consideration Liabilities** - The Company recorded income of \$4.5 million and \$2.2 million in the first quarter of 2021 and 2020, respectively, related to changes in the fair value of its contingent consideration liabilities arising from acquisitions.

**Amortization of Intangible Assets** - The Company recorded amortization expense related to developed technology and patents in the amount of \$1.1 million and \$1.7 million in the first quarter of 2021 and 2020, respectively.

**Provision for Income Taxes** - The income tax impact of the expenses and gains discussed above is based upon the items' forecasted effect upon the Company's full year effective tax rate.

#### **EDWARDS LIFESCIENCES CORPORATION**

### Unaudited Reconciliation of GAAP to Non-GAAP Financial Information

(in millions, except per share and percentage data)

	Three Months Ended March 31, 2021								
	Net Sales	Gross Profit Margin	Operating Income	Net Income	Diluted EPS	Effective Tax Rate			
GAAP	\$1,216.6	75.9 %	\$ 383.5	\$ 338.2	\$ 0.54	13.1 %			
Non-GAAP adjustments: (A) (B)									
Intellectual property litigation expenses	_	_	6.4	5.3	0.01	0.1			
Change in fair value of contingent consideration liabilities	_	_	(4.5)	(4.1)	(0.01)	_			
Amortization of intangible assets		0.1	1.1	1.0					
Adjusted	\$1,216.6	76.0 %	\$ 386.5	\$ 340.4	\$ 0.54	13.2 %			

	Three Months Ended March 31, 2020							
	Net Sales	Gross Profit Margin	Operating Income	Net Income	Diluted EPS (C)	Effective Tax Rate		
GAAP	\$1,128.7	76.5 %	\$ 358.1	\$ 310.6	\$ 0.49	14.8 %		
Non-GAAP adjustments: (A) (B)								
Intellectual property litigation expenses		_	12.5	10.3	0.01	0.1		
Change in fair value of contingent consideration liabilities	_	_	(2.2)	(2.0)		_		
Amortization of intangible assets		0.2	1.7	1.5				
Adjusted	\$1,128.7	76.7 %	\$ 370.1	\$ 320.4	\$ 0.50	14.9 %		

<sup>(</sup>A) See description of non-GAAP adjustments on the "Non-GAAP Financial Information" page.

<sup>(</sup>B) The tax effect on non-GAAP adjustments is calculated based upon the impact of the relevant tax jurisdictions' statutory tax rates on the Company's estimated annual effective tax rate, or discrete rate in the quarter, as applicable. The impact on the effective tax rate is reflected on each individual non-GAAP adjustment line item.

<sup>(</sup>C) All 2020 per share amounts were adjusted for the May 29, 2020 three-for-one stock split.

# RECONCILIATION OF SALES BY PRODUCT GROUP AND REGION

					2020 Adjusted			
Sales by Product Group (QTD)	1Q 2021	1Q 2020	Change	GAAP Growth Rate*	FX Impact	1Q 2020 Adjusted Sales	Underlying Growth Rate *	
Transcatheter Aortic Valve Replacement	\$ 791.7	\$ 742.2	\$ 49.5	6.7 %	\$ 18.0	\$ 760.2	4.1 %	
Transcatheter Mitral and Tricuspid Therapies	16.3	10.5	5.8	56.7 %	0.7	11.2	46.1 %	
Surgical Structural Heart	213.0	193.4	19.6	10.1 %	6.4	199.8	6.7 %	
Critical Care	195.6	182.6	13.0	7.1 %	5.0	187.6	4.4 %	
Total	\$1,216.6	\$1,128.7	\$ 87.9	7.8 %	\$ 30.1	\$ 1,158.8	5.0 %	

					2020		
Sales by Region (QTD)	1Q 2021	1Q 2020	Change	GAAP Growth Rate*	FX Impact	1Q 2020 Adjusted Sales	Underlying Growth Rate *
United States	\$ 674.7	\$ 667.4	\$ 7.3	1.1 %	<u>s</u> —	\$ 667.4	1.1 %
Europe	280.0	249.3	30.7	12.4 %	22.2	271.5	3.2 %
Japan	132.3	110.0	22.3	20.2 %	4.1	114.1	16.3 %
Rest of World	129.6	102.0	27.6	27.0 %	3.8	105.8	23.0 %
International	541.9	461.3	80.6	17.5 %	30.1	491.4	10.7 %
Total	\$1,216.6	\$1,128.7	\$ 87.9	7.8 %	\$ 30.1	\$ 1,158.8	5.0 %

<sup>\*</sup> Numbers may not calculate due to rounding.