



Edwards

NEWS RELEASE

EDWARDS LIFESCIENCES REPORTS FIRST QUARTER RESULTS

4/26/2022

IRVINE, Calif., April 26, 2022 /PRNewswire/ -- Edwards Lifesciences (NYSE: EW) today reported financial results for the quarter ended March 31, 2022.

First Quarter Highlights and Outlook

- Q1 sales grew 10 percent to \$1.34 billion; underlying¹ 13 percent
- Q1 TAVR sales grew 11 percent; underlying 14 percent
- Q1 EPS was \$0.59; adjusted¹ EPS was \$0.60
- Full year 2022 financial guidance unchanged
- Surgical mitral tissue valve MITRIS RESILIA approved in the U.S.
- Repurchased approximately \$400 million of stock in Q1

"We were pleased with our first quarter results despite the pronounced impact that Omicron had on hospital capacity, resources, and procedure volumes in January. Our supply chain team delivered, and our field employees continued to support the skilled clinicians and patients who count on Edwards," said Michael A. Mussallem, chairman and CEO. "First quarter sales increased 13 percent and growth was balanced across all regions. We continue to believe that 2022 will be an important year for Edwards, as we expect low double-digit sales growth and

meaningful progress on our pursuit of significant opportunities to improve patient care."

Transcatheter Aortic Valve Replacement (TAVR)

In the first quarter, the company reported TAVR sales of \$881 million, a year-over-year increase of 11 percent, or 14 percent on an underlying basis. Globally, the company's average selling price and market position were stable. U.S. TAVR sales grew approximately 10 percent and adoption was broad-based across hospitals.

Outside the U.S., in the first quarter, Edwards' underlying TAVR sales grew approximately 20 percent on a year-over-year basis. The company continues to see excellent opportunities for international expansion as TAVR adoption remains low.

Edwards advanced two pivotal trials in the first quarter aiming to expand TAVR indications: the EARLY TAVR trial for the large group of patients with severe AS and no diagnosed symptoms, and the PROGRESS trial evaluating patients with moderate AS, which represents a group that is much larger than those with severe AS. Edwards also remains on track to begin treating patients in the second quarter in the ALLIANCE pivotal trial for the company's next generation TAVR technology, the SAPIEN X4 system.

The company continues to estimate that the global TAVR opportunity will double to \$10 billion by 2028, implying a low double-digit compounded annual growth rate.

Transcatheter Mitral and Tricuspid Therapies (TMTT)

Edwards continued to progress on three key value drivers in the first quarter: a portfolio of differentiated therapies, positive pivotal trial results to support approvals and adoption, and favorable real world clinical outcomes.

First quarter TMTT sales were \$27 million driven by the continued adoption of the company's PASCAL platform in Europe. The company remains on track for U.S. approval of the PASCAL Precision platform for patients with degenerative mitral regurgitation late this year. In addition, Edwards continues to expect a late 2022 approval for the EVOQUE tricuspid valve replacement system in Europe.

Edwards anticipates that the global TMTT opportunity will reach \$5 billion by 2028. The company 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 \$221 million, up 4 percent compared to the first quarter of 2021, or 6 percent on an underlying basis. Growth was driven by increased penetration of premium technologies and procedure growth. In the first quarter, the company announced U.S. FDA approval and commercial launch of the MITRIS RESILIA valve, designed for the heart's mitral position. RESILIA tissue demonstrates potential to help patients thrive without the quality-of-life compromises that may come from having a mechanical valve.

Critical Care sales were \$212 million for the quarter, representing an increase of 8 percent versus the first quarter of 2021, or 11 percent on an underlying basis. Sales growth was driven by balanced contributions from all product lines, led by continued strength of the state-of-the-art HemoSphere monitoring platform.

Additional Financial Results

For the quarter, the adjusted gross profit margin was 77.8 percent, compared to 76.0 percent in the same period last year. As expected, this improvement was driven by the positive impact from FX, primarily the strengthening of the dollar against the Euro and Yen.

Selling, general and administrative expenses in the first quarter were \$370 million, or 27.6 percent of sales, compared to \$331 million in the prior year. The year-over-year increase was primarily driven by field-based personnel-related costs and commercial activities in support of the company's growth.

Research and development expenses in the first quarter grew 10 percent to \$229 million, or 17.0 percent of sales, compared to \$207 million in the prior year. This increase was primarily the result of continued investments in the company's transcatheter innovations, including increased clinical trial activity.

Free cash flow for the first quarter was \$221 million, defined as cash flow from operating activities of \$294 million, less capital spending of \$73 million.

Cash, cash equivalents and short-term investments totaled \$1.5 billion as of March 31, 2022. In February, Edwards entered into and completed an accelerated share repurchase agreement for \$250 million. Additionally, during the first quarter, shares were purchased through pre-established 10b5-1 programs totaling \$155 million.

Outlook

Overall, the company is reaffirming sales guidance for all product groups. Full year 2022 sales are expected to grow at a low double-digit underlying rate to \$5.5 to \$6.0 billion, which includes an estimated negative year-over-year impact of \$170 million from foreign exchange. Additionally, the company continues to expect full year 2022 adjusted earnings per share of \$2.50 to \$2.65, representing mid-teens growth over 2021.

For the second quarter of 2022, the company projects total sales to be between \$1.36 and \$1.44 billion, and adjusted EPS of \$0.61 to \$0.69.

"Looking beyond 2022, we remain confident in our long-term strategy and our pipeline of innovative therapies. Our R&D targets breakthrough therapies that create significant value for patients and health systems, enabling strong organic sales growth," said Mussallem. "As we are hopeful the worst of the pandemic is behind us, we are constantly reminded of the importance of our work as we pursue solutions for patients with cardiovascular disease,

which continues to be the number one killer in the world."

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 2:00 p.m. PT to discuss its first quarter results. To participate in the conference call, dial (877) 704-2848 or (201) 389-0893. The call will also be available live and archived 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," "guidance," "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 2022 financial guidance, statements regarding the TAVR and TMTT opportunity and the international adoption of TAVR, the compounded annual growth rate, statements regarding transforming patient treatment, 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 the 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, 2021, and its 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, ALLIANCE, EARLY TAVR, EVOQUE, HemoSphere, MITRIS, MITRIS RESILIA, PASCAL, PASCAL Precision, PROGRESS, RESILIA, SAPIEN, and SAPIEN X4 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.

[1] "Adjusted" amounts are non-GAAP items. "Underlying" growth rates in this press release exclude foreign exchange fluctuations. Adjusted earnings per share is a non-GAAP item computed on a diluted basis and in this press release excludes intellectual property litigation expenses, amortization of intangible assets, and fair value adjustments to contingent consideration liabilities arising from acquisitions. See "Non-GAAP Financial Information" and reconciliation tables below.

EDWARDS LIFESCIENCES CORPORATION
Unaudited Consolidated Statements of Operations
(in millions, except per share data)

	Three Months Ended March 31,	
	2022	2021
Net sales	\$ 1,341.2	\$ 1,216.6
Cost of sales	299.3	293.4
Gross profit	1,041.9	923.2
Selling, general, and administrative expenses	370.3	330.8
Research and development expenses	228.6	207.0
Intellectual property litigation expenses, net	7.1	6.4
Change in fair value of contingent consideration liabilities	(2.9)	(4.5)
Operating income	438.8	383.5
Interest income, net	(0.6)	(0.3)
Other expense (income), net	3.3	(5.5)

Income before provision for income taxes	436.1	389.3
Provision for income taxes	62.5	51.1
Net income	\$ 373.6	\$ 338.2
<u>Earnings per share:</u>		
Basic	\$ 0.60	\$ 0.54
Diluted	\$ 0.59	\$ 0.54
<u>Weighted-average common shares outstanding:</u>		
Basic	622.1	623.2
Diluted	629.4	631.3
<u>Operating statistics</u>		
As a percentage of net sales:		
Gross profit	77.7%	75.9%
Selling, general, and administrative expenses	27.6%	27.2%
Research and development expenses	17.0%	17.0%
Operating income	32.7%	31.5%
Income before provision for income taxes	32.5%	32.0%
Net income	27.9%	27.8%
Effective tax rate	14.3%	13.1%

Note: Numbers may not calculate due to rounding.

EDWARDS LIFESCIENCES CORPORATION
Unaudited Balance Sheets
(in millions)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,030.9	\$ 862.8
Short-term investments	465.0	604.0
Accounts receivable, net	636.3	582.2
Other receivables	49.9	82.7

Inventories	730.6	726.7
Prepaid expenses	94.1	85.2
Other current assets	234.5	237.1
Total current assets	3,241.3	3,180.7
Long-term investments	1,623.7	1,834.2
Property, plant, and equipment, net	1,552.2	1,546.6
Operating lease right-of-use assets	90.1	92.1
Goodwill	1,166.3	1,167.9
Other intangible assets, net	322.0	323.6
Deferred income taxes	294.9	246.7
Other assets	129.4	110.8
Total assets	\$ 8,419.9	\$ 8,502.6

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities

Accounts payable and accrued liabilities	\$ 926.0	\$ 1,006.8
Operating lease liabilities	23.9	25.5
Total current liabilities	949.9	1,032.3
Long-term debt	595.9	595.7
Contingent consideration liabilities	59.1	62.0
Taxes payable	190.0	190.0
Operating lease liabilities	68.4	69.1
Uncertain tax positions	270.7	259.0
Litigation settlement accrual	181.3	191.3
Other liabilities	259.7	267.3
Total liabilities	2,575.0	2,666.7

Stockholders' equity

Common stock	642.9	642.0
Additional paid-in capital	1,769.4	1,700.4
Retained earnings	6,441.7	6,068.1
Accumulated other comprehensive loss	(186.6)	(157.7)
Treasury stock, at cost	(2,822.5)	(2,416.9)

Total stockholders' equity	5,844.9	5,835.9
Total liabilities and stockholders' equity	\$ 8,419.9	\$ 8,502.6

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 "underlying" when referring to non-GAAP sales and sales growth information, which excludes currency 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 currency exchange rates impact the comparative results and sales growth rates of the Company's underlying business. Management believes that excluding the impact of currency exchange rate fluctuations from its sales growth provides investors a more useful comparison to historical financial results. The impact of the 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, net - The Company incurred net intellectual property litigation expenses of \$7.1 million and \$6.4 million in the first quarter of 2022 and 2021, respectively.

Change in Fair Value of Contingent Consideration Liabilities - The Company recorded income of \$2.9 million and \$4.5 million in the first quarter of 2022 and 2021, 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 \$1.7 million and \$1.1 million in the first quarter of 2022 and 2021, 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. Adjustments to forecasted items unrelated to these expenses and gains, as well as impacts related to interim reporting, will have an effect on the income tax impact of these items in subsequent periods.

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, 2022					
	Net Sales	Gross Profit Margin	Operating Income	Net Income	Diluted EPS	Effective Tax Rate
GAAP	\$ 1,341.2	77.7%	\$ 438.8	\$ 373.6	\$ 0.59	14.3%
Non-GAAP adjustments: (A) (B)						
Intellectual property litigation expenses, net	—	—	7.1	5.8	0.01	0.1

Change in fair value of contingent consideration liabilities	—	—	(2.9)	(2.6)	—	—
Amortization of intangible assets	—	0.1	1.7	1.5	—	—
Adjusted	<u>\$ 1,341.2</u>	<u>77.8%</u>	<u>\$ 444.7</u>	<u>\$ 378.3</u>	<u>\$ 0.60</u>	<u>14.4%</u>
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Three Months Ended March 31, 2021						
	<u>Net Sales</u>	<u>Gross Profit Margin</u>	<u>Operating Income</u>	<u>Net Income</u>	<u>Diluted EPS</u>	<u>Effective Tax Rate</u>
GAAP	\$ 1,216.6	75.9%	\$ 383.5	\$ 338.2	\$ 0.54	13.1%
Non-GAAP adjustments: (A) (B)						
Intellectual property litigation expenses, net	—	—	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	<u>\$ 1,216.6</u>	<u>76.0%</u>	<u>\$ 386.5</u>	<u>\$ 340.4</u>	<u>\$ 0.54</u>	<u>13.2%</u>
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(A) See description of non-GAAP adjustments under "Non-GAAP Financial Information."

(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.

RECONCILIATION OF SALES BY PRODUCT GROUP AND REGION

Sales by Product Group (QTD)	1Q 2022	1Q 2021	Change	GAAP Growth Rate*	2021 Adjusted		Underlying Growth Rate *
					FX Impact	1Q 2021 Adjusted Sales	
Transcatheter Aortic Valve Replacement	\$ 881.3	\$ 791.7	\$ 89.6	11.3%	\$ (16.3)	\$ 775.4	13.7%
Transcatheter Mitral and Tricuspid Therapies	27.0	16.3	10.7	65.7%	(0.7)	15.6	73.0%
Surgical Structural Heart	220.8	213.0	7.8	3.7%	(5.4)	207.6	6.3%
Critical Care	212.1	195.6	16.5	8.4%	(4.5)	191.1	11.0%
Total	<u>\$ 1,341.2</u>	<u>\$ 1,216.6</u>	<u>\$ 124.6</u>	10.2%	<u>\$ (26.9)</u>	<u>\$ 1,189.7</u>	12.7%
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Sales by Region (QTD)	1Q 2022	1Q 2021	Change	GAAP Growth Rate*	2021 Adjusted		Underlying Growth Rate *
					FX Impact	1Q 2021 Adjusted Sales	

United States	\$ 749.5	\$ 674.7	\$ 74.8	11.1%	\$ —	\$ 674.7	11.1%
Europe	311.1	280.0	31.1	11.1%	(14.9)	265.1	17.5%
Japan	135.5	132.3	3.2	2.4%	(9.5)	122.8	10.4%
Rest of World	145.1	129.6	15.5	12.0%	(2.5)	127.1	14.3%
International	591.7	541.9	49.8	9.2%	(26.9)	515.0	14.9%
Total	\$ 1,341.2	\$ 1,216.6	\$ 124.6	10.2%	\$ (26.9)	\$ 1,189.7	12.7%

* Numbers may not calculate due to rounding.

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