



Edwards

Edwards Lifesciences Corporation
One Edwards Way · Irvine, CA USA · 92614
Phone: 949.250.2500 · Fax: 949.250.2525
www.edwards.com

FOR IMMEDIATE RELEASE

Media Contact: Sarah Huoh, 949-250-5070

Investor Contact: Mark Wilterding, 949-250-6826

EDWARDS LIFESCIENCES REPORTS FOURTH QUARTER RESULTS

IRVINE, Calif., January 30, 2020 — Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, today reported financial results for the quarter ended December 31, 2019.

Fourth Quarter Results and Outlook

- Q4 sales grew 20% to \$1.2 billion; underlying¹ sales grew 19%
- Q4 TAVR sales grew 29%; underlying sales grew 30%
- Q4 EPS was \$1.32; adjusted¹ EPS grew 25% to \$1.46
- Full year 2019 sales and earnings significantly exceeded original guidance
- 2020 guidance ranges increased: sales \$4.6 billion to \$5.0 billion; EPS \$6.15 to \$6.40
- SAPIEN 3 transcatheter heart valve received low risk indication expansion in Europe
- EVOQUE tricuspid early feasibility study receives FDA approval

“We are pleased to report robust fourth quarter performance that delivered 19 percent sales growth on an underlying basis, driven by our portfolio of innovative technologies. For the full year 2019, we reported 15 percent revenue growth on an underlying basis, with double-digit growth in each region,” said Michael A. Mussallem, chairman and CEO. “Most importantly, I’m proud to report we’re poised to help even more patients benefit from Edwards’ life-saving technologies. We invested aggressively in transformative therapies in 2019 and this will continue in 2020 as our commitment has never been greater.”

2019 Full Year Results

Sales for the year ended December 31, 2019 were \$4.3 billion, up 17 percent over the prior year, or 15 percent on an underlying basis. Diluted earnings per share for 2019 were \$4.93, while adjusted earnings per share grew 19 percent, to \$5.57.

Transcatheter Aortic Valve Replacement (TAVR)

The company reported fourth quarter global TAVR sales of \$763 million, a year-over-year increase of approximately 30 percent on both a reported and underlying basis with impressive strength in the U.S. Global average selling prices remained stable.

In the fourth quarter, the company estimates U.S. TAVR procedures grew approximately 40 percent on a year-over-year basis and Edwards' growth was comparable. Outside the U.S., the company estimates that total TAVR procedures grew in the high-teens on a year-over-year basis and Edwards' growth was comparable. As previously reported, Edwards became the first company to receive CE Mark for TAVR in Europe for the treatment of patients diagnosed with severe aortic stenosis who are at low risk for open-heart surgery.

Transcatheter Mitral and Tricuspid Therapies (TMTT)

TMTT is on track to achieve the milestones discussed at the company's recent Investor Conference, including executing four pivotal studies. In addition, the company announced that the EVOQUE tricuspid replacement valve system has recently received U.S. Food and Drug Administration (FDA) approval for an Early Feasibility Study and a "breakthrough device" designation, a program intended to help patients receive more timely access to designated medical technologies.

Full year 2019 TMTT sales of \$28 million came in below the original guidance of approximately \$40 million as the company continued to execute a disciplined introduction and premium pricing strategy of the PASCAL system, which moderated European site activation. Fourth quarter sales of \$7 million were negatively impacted by the voluntary PASCAL system field corrective action completed in the quarter. PASCAL clinical outcomes continue to be favorable and physician feedback remains positive. As the PASCAL system roll-out expands, the company will remain focused on procedural success and differentiated patient outcomes.

Surgical Structural Heart and Critical Care

Surgical Structural Heart sales for the quarter were \$205 million, down one percent compared to the fourth quarter of 2018, and down three percent on an underlying basis. The sales decline was the result of lower surgical aortic valve procedures in the U.S. as TAVR adoption increased, partially offset by continued strong adoption of the company's premium high-value technologies.

Critical Care sales were \$199 million for the quarter, representing an increase of 12 percent versus the fourth quarter of 2018 or eight percent on an underlying basis. This performance was driven by strong demand for the HemoSphere advance monitoring platform and continued adoption of Smart Recovery. Growth in the quarter was led by sales in the U.S.

Additional Financial Results

For the quarter, the company's adjusted gross profit margin was 75.8 percent, compared to 76.1 percent in the same period last year. This reduction was driven by spending in support of the new European medical device regulations and one-time costs associated with migrating Cardioband production from Israel to Ireland, partially offset by the benefit of a more profitable product mix.

Selling, general and administrative expenses increased 21 percent to \$347 million for the quarter, driven by increased field clinical personnel to support TAVR cases in the U.S. and TMTT cases in Europe, as well as accelerated actions related to disease awareness and therapy adoption.

Research and development for the fourth quarter increased 19 percent to \$194 million, or 16.5 percent of sales. This increase was primarily the result of continued investments in the company's transcatheter structural heart programs, including spending on clinical trials.

Free cash flow for the fourth quarter was \$328 million, defined as cash flow from operating activities of \$399 million, less capital spending of \$71 million.

Cash, cash equivalents and short-term investments totaled \$1.5 billion at December 31, 2019. Total debt was \$594 million.

Outlook

Overall, 2020 sales guidance for Edwards is now expected to be \$4.6 to \$5.0 billion versus the company's previous range of \$4.5 to \$5.0 billion. Additionally, the company now expects full year 2020 adjusted earnings per share of \$6.15 to \$6.40 versus previous guidance of \$6.05 to \$6.30.

For the first quarter of 2020, the company projects total sales to be between \$1.15 and \$1.2 billion, and adjusted EPS of \$1.49 to \$1.59.

"We were very proud of the significant progress we made in advancing transformational therapies in 2019, as well as our strong financial performance. We are enthusiastic about the future of transcatheter-based technologies, and the promise of treating the many structural heart patients still in need, which positions us very well for 2020 and beyond. We firmly believe our patient-focused innovation strategy can transform care and bring value to patients, healthcare systems, and shareholders," said Mussallem.

About Edwards Lifesciences

Edwards Lifesciences, based in Irvine, Calif., is the global leader in patient-focused medical innovations for structural heart disease and critical care monitoring. Driven by a passion to help patients, the company collaborates with the world's leading clinicians and researchers to address unmet healthcare needs, working to improve patient outcomes and enhance lives. For more information, visit www.Edwards.com and follow us on Twitter @EdwardsLifesci.

Conference Call and Webcast Information

Edwards Lifesciences will be hosting a conference call today at 2:00 p.m. PT to discuss its fourth 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 13694541. 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,” “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, estimates of the company’s competitive position, first quarter and full year 2020 financial guidance, statements regarding the company’s milestones, the company’s focus on procedural success and patient outcomes, future therapy opportunities and information in the Outlook section. 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 and difficult to predict. 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 uncertainties associated with clinical trial or commercial results or new product approvals and therapy adoption, particularly in TAVR and TMTT; 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, including its Annual Report on Form 10-K for the year ended December 31, 2018. These filings, along with important safety information about our products, may be found at edwards.com.

Edwards, Edwards Lifesciences, the stylized E logo, Cardioband, Edwards SAPIEN, Edwards SAPIEN 3, SAPIEN 3, EVOQUE, HemoSphere, and PASCAL, 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. Adjusted sales, or “underlying” growth rates, in this press release excludes foreign exchange rate fluctuations, the positive impact of TAVR stocking sales in Germany and the negative impact of de-stocking, the conversion to a consignment inventory system for surgical structural heart (“Surgical”), and includes the prior year sales results of a business acquired in the current year. Adjusted earnings per share is a non-GAAP item computed on a diluted basis and in this press release excludes intellectual property litigation income and expenses, amortization of intangible assets, fair value adjustments to contingent consideration liabilities arising from acquisitions, charges associated with an intangible asset impairment, TAVR inventory write offs and the purchase of intellectual property, the conversion to a consignment inventory system for Surgical, a significant pension curtailment gain, the positive impact of TAVR stocking sales in Germany and the negative impact of de-stocking, and the impact from implementation of tax law changes and settlements. 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 December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Net sales	\$ 1,174.1	\$ 977.7	\$ 4,348.0	\$ 3,722.8
Cost of sales	286.2	234.7	1,114.4	939.4
Gross profit	887.9	743.0	3,233.6	2,783.4
Selling, general, and administrative expenses	347.2	288.1	1,242.2	1,088.5
Research and development expenses	193.9	163.1	752.7	622.2
Intellectual property litigation expenses	13.9	194.9	33.4	214.0
Change in fair value of contingent consideration liabilities, net	(18.5)	(14.0)	(6.1)	(5.7)
Special charges	40.6	116.2	64.6	116.2
Operating income (loss)	310.8	(5.3)	1,146.8	748.2
Interest income, net	(4.3)	(1.8)	(11.5)	(2.1)
Special gain	—	—	—	(7.1)
Other income, net	(0.4)	(1.7)	(8.2)	(4.0)
Income before provision for (benefit from) income taxes	315.5	(1.8)	1,166.5	761.4
Provision for (benefit from) income taxes	35.3	(8.8)	119.6	39.2
Net income	<u>\$ 280.2</u>	<u>\$ 7.0</u>	<u>\$ 1,046.9</u>	<u>\$ 722.2</u>
<u>Earnings per share:</u>				
Basic	\$ 1.34	\$ 0.03	\$ 5.03	\$ 3.45
Diluted	\$ 1.32	\$ 0.03	\$ 4.93	\$ 3.38
<u>Weighted-average common shares outstanding:</u>				
Basic	208.8	208.1	208.3	209.2
Diluted	212.6	212.2	212.2	213.6
<u>Operating statistics</u>				
As a percentage of net sales:				
Gross profit	75.6%	76.0 %	74.4%	74.8%
Selling, general, and administrative expenses	29.6%	29.5 %	28.6%	29.2%
Research and development expenses	16.5%	16.7 %	17.3%	16.7%
Operating income (loss)	26.5%	(0.5)%	26.4%	20.1%
Income before provision for (benefit from) income taxes	26.9%	(0.2)%	26.8%	20.5%
Net income	23.9%	0.7 %	24.1%	19.4%
Effective tax rate	11.2%	488.9 %	10.3%	5.1%

Note: Numbers may not calculate due to rounding.

EDWARDS LIFESCIENCES CORPORATION
Unaudited Balance Sheets
(in millions)

	December 31,	
	2019	2018
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,179.1	\$ 714.1
Short-term investments	337.8	242.4
Accounts and other receivables, net	599.1	537.3
Inventories, net	640.9	607.0
Prepaid expenses	59.1	54.3
Other current assets	168.0	131.8
Total current assets	<u>2,984.0</u>	<u>2,286.9</u>
Long-term investments	585.5	506.3
Property, plant, and equipment, net	1,060.3	867.5
Operating lease right-of-use assets	80.1	—
Goodwill	1,167.7	1,112.2
Other intangible assets, net	336.5	343.2
Deferred income taxes	172.2	174.0
Other assets	101.8	33.6
Total assets	<u>\$ 6,488.1</u>	<u>\$ 5,323.7</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 876.9	\$ 876.6
Operating lease liabilities	25.5	—
Total current liabilities	<u>902.4</u>	<u>876.6</u>
Long-term debt	594.4	593.8
Contingent consideration liabilities	172.5	178.6
Taxes payable	236.6	259.4
Operating lease liabilities	58.9	—
Uncertain tax positions	171.7	124.9
Other long-term liabilities	203.3	150.0
Stockholders' equity		
Common stock	218.1	215.2
Additional paid-in capital	1,623.3	1,384.4
Retained earnings	3,741.6	2,694.7
Accumulated other comprehensive loss	(156.0)	(138.5)
Treasury stock, at cost	(1,278.7)	(1,015.4)
Total stockholders' equity	<u>4,148.3</u>	<u>3,140.4</u>
Total liabilities and stockholders' equity	<u>\$ 6,488.1</u>	<u>\$ 5,323.7</u>

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 conversion to a consignment inventory system for surgical structural heart ("Surgical"), the positive impact of transcatheter aortic valve replacement ("TAVR") stocking sales in Germany and the negative impact of de-stocking, and includes the prior year sales results of a business acquired in the current year. The Company uses the term "adjusted" to also exclude intellectual property litigation income and expenses, amortization of intangible assets, fair value adjustments to contingent consideration liabilities arising from acquisitions, impairment of long-lived assets, the positive impact of TAVR stocking sales in Germany and the negative impact of de-stocking, the conversion to a consignment inventory system for Surgical, significant pension curtailment gains, charges associated with TAVR inventory write offs and the purchase of intellectual property, and the impact from implementation of tax law changes and settlements.

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

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

Fluctuations in 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. 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:

Impairment of Long-lived Assets - The Company recorded a \$40.6 million charge in the fourth quarter of 2019 and a \$116.2 million charge in the fourth quarter of 2018 related to the other-than-temporary impairment of certain developed technology and in-process research and development acquired as part of the acquisition of Valtech Cardio Ltd.

TAVR Inventory Write Off - The Company recorded a \$46.2 million charge in the second quarter of 2019 and a \$26.9 million charge in the third quarter of 2019, primarily comprised of the write off of inventory in response to strategic decisions regarding its TAVR portfolio.

Intellectual Property Litigation Expenses - The Company incurred intellectual property litigation expenses of \$4.6 million and \$5.7 million in the first quarter of 2019 and 2018, respectively, \$7.0 million and \$5.5 million in the second quarter of 2019

and 2018, respectively, \$7.9 million and \$7.9 million in the third quarter of 2019 and 2018, respectively, and \$13.9 million and \$12.2 million in the fourth quarter of 2019 and 2018, respectively. In addition, in the fourth quarter of 2018, the Company recorded a \$182.7 million charge related to a litigation settlement, including the write off of certain patents.

Change in Fair Value of Contingent Consideration Liabilities, net - The Company recorded expenses related to changes in the fair value of its contingent consideration liabilities arising from acquisitions in the amount of \$6.7 million and \$3.8 million in the first quarter of 2019 and 2018, respectively, \$8.0 million and \$10.9 million in the second quarter of 2019 and 2018, respectively, income of \$2.3 million and \$6.4 million in the third quarter of 2019 and 2018, respectively, and income of \$18.5 million and \$14.0 million in the fourth quarter of 2019 and 2018, respectively.

Amortization of Intangible Assets - The Company recorded amortization expense related to developed technology, patents and trademarks in the amount of \$0.5 million and \$0.6 million in the first quarter of 2019 and 2018, respectively, \$1.2 million and \$0.7 million in the second quarter of 2019 and 2018, respectively, \$1.3 million and \$0.6 million in the third quarter of 2019 and 2018, respectively, and \$1.6 million and \$0.6 million in the fourth quarter of 2019 and 2018, respectively.

Purchase of Intellectual Property - The Company recorded a \$24.0 million charge in the first quarter of 2019 related to the acquisition of early-stage transcatheter intellectual property and associated clinical and regulatory experience.

Surgical Consignment Conversion - In the first, second, third and fourth quarters of 2018, the Company recorded a sales return reserve of \$34.7 million (\$30.8 million, net of related costs), \$28.4 million (\$24.6 million, net of related costs), \$14.4 million (\$12.9 million, net of related costs), and \$5.0 million (\$4.2 million, net of related costs), respectively, related to its conversion to a consignment inventory system for surgical heart valves.

TAVR Germany Stocking Sales - In the first quarter of 2017, the Company recorded \$61.8 million in net stocking sales (\$48.0 million, net of related costs) to customers in Germany, as these customers elected to purchase additional inventory in anticipation of a potential supply interruption resulting from intellectual property litigation. In the first quarter of 2018, these customers consumed on a net basis \$8.0 million (\$6.0 million, net of related costs) of their stocking inventory.

Pension Curtailment Gain - The Company recorded a \$7.1 million gain in the first quarter of 2018 related to the curtailment of its defined benefit plan resulting from the closure of its manufacturing plant in Switzerland.

Provision for Income Taxes - During the first quarter of 2018, the Company recorded a \$24.0 million tax expense to adjust its estimated provisional amounts related to the implementation of U.S. tax law changes. During the second quarter of 2018, the Company recorded a \$36.1 million tax benefit related to the settlement of tax audits and a \$17.3 million benefit related to the reorganization of a foreign entity and adjustments to estimated provisional amounts resulting from the U.S. tax law changes. During each of the third and fourth quarters of 2018, the Company recorded an additional \$4.6 million benefit related to the reorganization of a foreign entity. 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.

Adjusted Free Cash Flow - The Company defines free cash flow as cash flows from operating activities less capital expenditures. During 2019, the Company excluded from its calculation payments related to a litigation settlement, net of the associated tax benefit. During 2018, the Company excluded from its calculation payments related to tax audit settlements and the repatriation tax resulting from U.S. tax law changes.

EDWARDS LIFESCIENCES CORPORATION
Unaudited Reconciliation of GAAP to Non-GAAP Financial Information

(in millions, except per share and percentage data)

	Three Months Ended December 31, 2019					
	Net Sales	Gross Profit Margin	Operating Income	Net Income	Diluted EPS	Effective Tax Rate
GAAP	\$1,174.1	75.6%	\$ 310.8	\$ 280.2	\$ 1.32	11.2%
<u>Non-GAAP adjustments:</u> ^{(A)(C)}						
Impairment of long-lived assets	—	—	40.6	40.6	0.19	(1.0)
Intellectual property litigation expenses	—	—	13.9	13.9	0.04	0.6
Change in fair value of contingent consideration liabilities, net	—	—	(18.5)	(18.5)	(0.09)	0.7
Amortization of intangible assets	—	0.2	1.6	1.6	0.01	—
Provision for income taxes						
Tax effect on non-GAAP adjustments ^(B)	—	—	—	(4.9)	—	—
Prior period ongoing tax impacts ^(D)	—	—	—	(3.3)	(0.01)	0.8
Adjusted	<u>\$1,174.1</u>	<u>75.8%</u>	<u>\$ 348.4</u>	<u>\$ 309.6</u>	<u>\$ 1.46</u>	<u>12.3%</u>

	Three Months Ended December 31, 2018					
	Net Sales	Gross Profit Margin	Operating Income	Net Income	Diluted EPS	Effective Tax Rate
GAAP	\$ 977.7	76.0%	\$ (5.3)	\$ 7.0	\$ 0.03	488.9%
<u>Non-GAAP adjustments:</u> ^{(A)(C)}						
Impairment of long-lived assets	—	—	116.2	116.2	0.52	(87.9)
Surgical consignment conversion	5.0	—	4.2	4.2	0.01	(129.4)
Intellectual property litigation expenses	—	—	194.9	194.9	0.70	(179.0)
Change in fair value of contingent consideration liabilities, net	—	—	(14.0)	(14.0)	(0.07)	(77.4)
Amortization of intangible assets	—	0.1	0.6	0.6	—	46.8
Provision for income taxes						
Tax effect on non-GAAP adjustments ^(B)	—	—	—	(55.8)	—	—
Impacts from U.S. tax legislation	—	—	—	(4.6)	(0.02)	(45.8)
Prior period ongoing tax impacts ^(D)	—	—	—	0.1	—	1.0
Adjusted	<u>\$ 982.7</u>	<u>76.1%</u>	<u>\$ 296.6</u>	<u>\$ 248.6</u>	<u>\$ 1.17</u>	<u>17.2%</u>

Twelve Months Ended December 31, 2019						
	Net Sales	Gross Profit Margin	Operating Income	Net Income	Diluted EPS	Effective Tax Rate
GAAP	\$4,348.0	74.4%	\$ 1,146.8	\$1,046.9	\$ 4.93	10.3%
Non-GAAP adjustments: ^{(A)(C)}						
Impairment of long-lived assets	—	—	40.6	40.6	0.19	(0.5)
TAVR inventory write off	—	1.7	73.1	73.1	0.26	1.0
Intellectual property litigation expenses	—	—	33.4	33.4	0.12	0.4
Change in fair value of contingent consideration liabilities, net	—	—	(6.1)	(6.1)	(0.04)	0.1
Amortization of intangible assets	—	0.1	4.6	4.6	0.02	(0.1)
Purchase of intellectual property	—	—	24.0	24.0	0.09	0.3
Provision for income taxes						
Tax effect on non-GAAP adjustments ^(B)	—	—	—	(28.8)	—	—
Prior period ongoing tax impacts ^(D)	—	—	—	(4.8)	—	—
Adjusted	\$4,348.0	76.2%	\$ 1,316.4	\$1,182.9	\$ 5.57	11.5%

Twelve Months Ended December 31, 2018						
	Net Sales	Gross Profit Margin	Operating Income	Net Income	Diluted EPS	Effective Tax Rate
GAAP	\$3,722.8	74.8%	\$ 748.2	\$ 722.2	\$ 3.38	5.1%
Non-GAAP adjustments: ^{(A)(C)}						
Impairment of long-lived assets	—	—	116.2	116.2	0.51	0.1
SHV consignment conversion	82.5	0.3	72.5	72.5	0.26	1.2
TAVR Germany stocking sales	8.0	—	6.0	6.0	0.02	0.1
Intellectual property litigation expenses	—	—	214.0	214.0	0.77	3.1
Change in fair value of contingent consideration liabilities, net	—	—	(5.7)	(5.7)	(0.04)	0.2
Amortization of intangible assets	—	—	2.5	2.5	0.01	—
Pension curtailment gain	—	—	—	(7.1)	(0.03)	—
Provision for income taxes						
Tax effect on non-GAAP adjustments ^(B)	—	—	—	(78.0)	—	—
Tax audit settlements	—	—	—	(36.1)	(0.17)	3.4
Impacts from U.S. tax legislation	—	—	—	(2.5)	(0.01)	0.2
Prior period ongoing tax impacts ^(D)	—	—	—	0.3	—	—
Adjusted	\$3,813.3	75.1%	\$ 1,153.7	\$1,004.3	\$ 4.70	13.4%

^(A) See description of non-GAAP adjustments on the "Non-GAAP Financial Information" page.

^(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 tax effect on the TAVR Germany stocking sales adjustment is calculated using the global effective tax rate.

^(C) All amounts are tax effected, 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.

^(D) Quarterly adjustment required to spread the full year tax impact of previously reported items.

RECONCILIATION OF GAAP OPERATING CASH FLOW TO ADJUSTED FREE CASH FLOW

	Twelve Months Ended December 31,	
	2019	2018
Net cash provided by operating activities	\$ 1,179.4	\$ 926.8
Capital expenditures	(254.4)	(238.7)
Litigation settlement, net of tax benefit	138.3	—
Tax audit settlements	—	56.7
Repatriation tax payments	—	41.0
Adjusted Free Cash Flow ^(A)	<u>\$ 1,063.3</u>	<u>\$ 785.8</u>

^(A) See description of “Adjusted Free Cash Flow” on the Non-GAAP Financial Information page.

RECONCILIATION OF SALES BY PRODUCT GROUP AND REGION

Sales by Product Group (QTD)	2018 Adjusted									Underlying Growth Rate *
	4Q 2019	4Q 2018	Change	GAAP Growth Rate*	CASMED Acquisition	Surgical Consignment Conversion	Germany Stocking	FX Impact	4Q 2018 Adjusted Sales	
Transcatheter Aortic Valve Replacement	\$ 762.5	\$ 591.6	\$ 170.9	28.9 %	\$ —	\$ —	\$ —	\$ (3.2)	\$ 588.4	29.6 %
Transcatheter Mitral and Tricuspid Therapies	7.2	0.8	6.4	841.1 %	—	—	—	—	0.8	NM
Surgical Structural Heart	205.1	207.2	(2.1)	(1.0)%	—	5.0	—	(1.0)	211.2	(2.9)%
Critical Care	199.3	178.1	21.2	11.9 %	5.8	—	—	—	183.9	8.5 %
Critical Care excluding CASMED	192.8	178.1	14.7	8.2 %	—	—	—	—	178.1	8.3 %
CASMED	6.5	—	6.5	NA	5.8	—	—	—	5.8	13.1 %
Total	\$1,174.1	\$ 977.7	\$ 196.4	20.1 %	\$ 5.8	\$ 5.0	\$ —	\$ (4.2)	\$ 984.3	19.3 %
Total Sales excluding CASMED	\$1,167.6	\$ 977.7	\$ 189.9	19.4 %	\$ —	\$ 5.0	\$ —	\$ (4.2)	\$ 978.5	19.3 %

Sales by Product Group (YTD)	2018 Adjusted									Underlying Growth Rate *
	YTD 4Q 2019	YTD 4Q 2018	Change	GAAP Growth Rate*	CASMED Acquisition	Surgical Consignment Conversion	Germany Stocking	FX Impact	YTD 4Q 2018 Adjusted Sales	
Transcatheter Aortic Valve Replacement	\$2,737.9	\$2,283.8	\$ 454.1	19.9%	\$ —	\$ —	\$ 8.0	\$ (32.7)	\$ 2,259.1	21.2%
Transcatheter Mitral and Tricuspid Therapies	28.2	2.9	25.3	NM	—	—	—	(0.1)	2.8	NM
Surgical Structural Heart	841.7	761.6	80.1	10.5%	—	82.5	—	(14.5)	829.6	1.5%
Critical Care	740.2	674.5	65.7	9.7%	15.3	—	—	(9.1)	680.7	8.8%
Critical Care excluding CASMED	723.4	674.5	48.9	7.3%	—	—	—	(9.1)	665.4	8.7%
CASMED	16.8	—	16.8	NA	15.3	—	—	—	15.3	10.0%
Total	\$4,348.0	\$3,722.8	\$ 625.2	16.8%	\$ 15.3	\$ 82.5	\$ 8.0	\$ (56.4)	\$ 3,772.2	15.3%
Total Sales excluding CASMED	\$4,331.2	\$3,722.8	\$ 608.4	16.3%	\$ —	\$ 82.5	\$ 8.0	\$ (56.4)	\$ 3,756.9	15.3%

Sales by Region (QTD)	2018 Adjusted									Underlying Growth Rate *
	4Q 2019	4Q 2018	Change	GAAP Growth Rate*	CASMED Acquisition	Surgical Consignment Conversion	Germany Stocking	FX Impact	4Q 2018 Adjusted Sales	
United States	\$ 697.2	\$ 545.0	\$ 152.2	27.9%	\$ 4.8	\$ 5.0	\$ —	\$ —	\$ 554.8	25.7%
Europe	242.2	225.8	16.4	7.3%	0.3	—	—	(6.6)	219.5	10.4%
Japan	120.3	107.3	13.0	12.1%	0.3	—	—	4.2	111.8	7.5%
Rest of World	114.4	99.6	14.8	14.7%	0.4	—	—	(1.8)	98.2	16.6%
International	476.9	432.7	44.2	10.2%	1.0	—	—	(4.2)	429.5	11.1%
Total	\$1,174.1	\$ 977.7	\$ 196.4	20.1%	\$ 5.8	\$ 5.0	\$ —	\$ (4.2)	\$ 984.3	19.3%

Sales by Region (YTD)	2018 Adjusted									Underlying Growth Rate *
	YTD 4Q 2019	YTD 4Q 2018	Change	GAAP Growth Rate*	CASMED Acquisition	Surgical Consignment Conversion	Germany Stocking	FX Impact	YTD 4Q 2018 Adjusted Sales	
United States	\$2,532.7	\$2,055.3	\$ 477.4	23.2%	\$ 12.8	\$ 82.5	\$ —	\$ —	\$ 2,150.6	17.8%
Europe	941.2	885.1	56.1	6.4%	1.1	—	8.0	(44.8)	849.4	10.8%
Japan	444.7	396.8	47.9	12.1%	0.5	—	—	4.5	401.8	10.6%
Rest of World	429.4	385.6	43.8	11.3%	0.9	—	—	(16.1)	370.4	15.9%
International	1,815.3	1,667.5	147.8	8.9%	2.5	—	8.0	(56.4)	1,621.6	11.9%
Total	\$4,348.0	\$3,722.8	\$ 625.2	16.8%	\$ 15.3	\$ 82.5	\$ 8.0	\$ (56.4)	\$ 3,772.2	15.3%

* Numbers may not calculate due to rounding.

NM - Not meaningful