

NEWS RELEASE

Orthofix Reports Fourth Quarter and Fiscal Year 2020 Results

2/26/2021

- Fourth quarter net sales of \$117.6 million, within 3% of our 2019 results
- US Spine implant sales grew 11% compared to fourth quarter 2019, driven by record M6-C artificial cervical disc performance
- Strong cash flow performance in the quarter, free cash flow of \$17.9 million
- FITBONE® intramedullary lengthening and deformity system receives FDA clearance for pediatric indication

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix Medical Inc. (NASDAQ:OFIX) today reported its financial results for the fourth quarter and fiscal year ended December 31, 2020. Net sales for the fourth quarter were \$117.6 million, earnings (loss) per share ("EPS") was \$(0.48) and adjusted EPS was \$0.44. For fiscal year 2020, net sales were \$406.6 million, EPS was \$0.13 and adjusted EPS was \$0.26.

"We were very pleased with our performance during the fourth quarter both from a financial and operating perspective. We were able to drive revenue to levels approaching 2019 while continuing to strengthen our organization during the continued disruption from restrictions on elective procedures globally," said Orthofix President and Chief Executive Officer Jon Serbousek.

"Although early 2021 has seen some significant COVID and winter weather headwinds, looking ahead, we are very excited about the future of Orthofix. We are now moving our transformation into an execution phase, and we look forward to leveraging the new capabilities we built throughout 2020 to drive growth and pursue high value solutions for patients, surgeons, and hospitals around the world. A great example is our recent expanded FDA clearance for the FITBONE® system, making it the only pediatric lengthening nail in the U.S., and an important addition to our pediatric portfolio."

Financial Results Overview

Fourth Quarter

The following table provides net sales by major product category by reporting segment:

Three Months Ended December 31,

(Unaudited, U.S. Dollars, in thousands)	2020	2019	Change	Constant Currency Change
Bone Growth Therapies	\$ 50,508	\$ 50,953	(0.9%)	(0.9%)
Spinal Implants	27,832	25,468	9.3%	8.6%
Biologics	15,163	16,712	(9.3%)	(9.3%)
Global Spine	93,503	93,133	0.4%	0.2%
Global Extremities	24,116	28,361	(15.0%)	(18.4%)
Net sales	\$ 117,619	\$ 121,494	(3.2%)	(4.1%)

Gross profit decreased \$6.8 million to \$88.5 million. Gross margin decreased to 75.3% compared to 78.4% in the prior year period.

Net loss was \$(9.4) million, or \$(0.48) per share, compared to net income of \$11.7 million, or \$0.60 per share in the prior year period. Adjusted net income was \$8.6 million, or \$0.44 per share, compared to adjusted net income of \$9.9 million, or \$0.51 per share in the prior year period.

EBITDA was \$14.2 million, compared to \$11.3 million in the prior year period. Adjusted EBITDA was \$22.1 million, or 18.8% of net sales, compared to \$22.5 million, or 18.5% of net sales, in the prior year period.

Fiscal Year 2020

The following table provides net sales by major product category by reporting segment:

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(U.S. Dollars, in thousands)	2020	2019	Change	Constant Currency Change
Bone Growth Therapies	\$ 171,396	\$ 197,181	(13.1%)	(13.1%)
Spinal Implants	94,857	94,544	0.3%	0.2%
Biologics	55,482	65,496	(15.3%)	(15.3%)
Global Spine	321,735	357,221	(9.9%)	(10.0%)
Global Extremities	84,827	102,734	(17.4%)	(18.2%)
Net sales	\$ 406,562	\$ 459,955	(11.6%)	(11.8%)

Gross profit decreased \$54.7 million to \$304.7 million. Gross margin decreased to 74.9% compared to 78.1% in the prior year period.

Net income was \$2.5 million, or \$0.13 per share, compared to a net loss of \$(28.5) million, or \$(1.51) per share in the prior year period. Adjusted net income was \$5.1 million, or \$0.26 per share, compared to adjusted net income of \$28.4 million, or \$1.47 per share in the prior year period.

EBITDA was \$32.7 million, compared to \$(2.2) million in the prior year period. Adjusted EBITDA was \$47.6 million, or 11.7% of net sales, compared to \$75.7 million, or 16.5% of net sales, in the prior year period.

Liquidity

As of December 31, 2020, cash, cash equivalents, and restricted cash totaled \$96.8 million compared to \$70.4 million as of December 31, 2019. As of December 31, 2020, the Company had no borrowings under its five year \$300 million secured revolving credit facility. Cash flow from operations increased \$42.2 million to \$74.3 million, while free cash flow increased \$45.7 million to \$57.2 million for the year ended December 31, 2020.

COVID-19 Impact and 2021 Outlook

The global Coronavirus Disease 2019 ("COVID-19") pandemic has significantly affected the Company's customers, communities, employees and business operations. The pandemic has led to the cancellation or deferral of elective surgeries and procedures, restrictions on travel, the implementation of physical distancing measures, and the temporary or permanent closure of businesses. However, the Company remains focused on protecting the health and wellbeing of its employees, partners, patients, and the communities in which it operates while assuring the continuity of its business operations.

At the beginning of the first quarter of 2021, COVID-19 restrictions have increased over December 2020 measures and from January through early February we saw procedural volume declines of approximately 15%. In addition, the weather emergency experienced last week will likely have an additional negative impact on our business for the first quarter. While we expect improvements in March, we still anticipate a modest impact from COVID-19 related restrictions into the second quarter. The third and fourth quarters are expected to show stronger growth when compared to the second half of 2019 as a result of expected rebounds in procedural volumes and case complexity.

As of the date hereof, the Company expects the following net sales results for the year ended December 31, 2021, and for the quarter ended March 31, 2021, including the impact of any expected changes in foreign currency exchange rates:

	2	.021 Full Year	Outlook	Q1 2021 O	utlook
(Unaudited, U.S. Dollars, in millions, except per share					
data)		Low	High	Low	High
Net sales	\$	445.0 1\$	460.0 1\$	95.0 2\$	96.0 2
Adjusted EBITDA	\$	50.0 3\$	54.0 3		
Adjusted EPS	\$	0.45 4\$	0.55 4		

- 1 Represents a year-over-year increase of 9.5% to 13.1% on a reported basis
- 2 Represents a year-over-year decrease of 9.4% to 8.4% on a reported basis
- 3 Represents a year-over-year increase of 5.0% to 13.4%
- 4 Represents a year-over-year increase of 73.1% to 111.5%

Guidance for the quarter ended March 31, 2021 is provided for increased clarity during the continued impact from COVID-19 and recent severe national weather events. However, the Company remains focused on its longer-term results and, assuming current improvements continue, the Company does not expect to provide quarterly guidance prospectively.

The Company does not provide U.S. GAAP financial measures, other than net sales, on a forward-looking basis because the Company is unable to predict with reasonable certainty the ultimate outcome of legal proceedings, unusual gains and losses, acquisition-related expenses, accounting fair value adjustments, and other such items without unreasonable effort. These items are uncertain, depend on various factors, and could be material to the Company's results computed in accordance with U.S. GAAP.

Conference Call

Orthofix will host a conference call today at 8:30 AM Eastern time to discuss the Company's financial results for the fourth quarter and fiscal year 2020. Interested parties may access the conference call by dialing (833) 670-0709 in the U.S. and (343) 761-2533 outside the U.S., and referencing the conference ID 6288562. A replay of the call will be available for three weeks by dialing (800) 585-8367 in the U.S. and (416) 621-4642 outside the U.S., and entering the conference ID 6288562. A webcast of the conference call may be accessed at ir.Orthofix.com/events-and-presentations.

About Orthofix

Orthofix Medical Inc. is a global medical device and biologics company with a spine and extremities focus. The Company's mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patients' lives. Headquartered in Lewisville, Texas, Orthofix's spine and orthopedic extremities products are distributed in over 70 countries via the Company's sales representatives and distributors. For more information, please visit www.orthofix.com.

Forward-Looking Statements

This communication contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "projects," "intends," "predicts," "potential," or "continue" or other comparable terminology. These forward-looking statements are not guarantees

of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2020 (the "2020 Form 10-K"). Factors that could cause or contribute to such differences may include, but are not limited to, (i) risks relating to the effects of the COVID-19 pandemic on our business, including (A) surgeries that use our products being delayed or cancelled as a result of hospitals and surgery centers being closed or limited to life-threatening and/or essential procedures, (B) portions of our global workforce being unable to work fully and/or effectively due to illness, quarantines, government actions (including "shelter in place" orders or advisories), facility closures or other reasons related to the pandemic, (C) disruptions to our supply chain, (D) customers and payors being unable to satisfy contractual obligations to us, including the ability to make timely payment for purchases, (E) general economic weakness in markets in which we operate affecting customer spending, and (F) other unpredictable aspects of the pandemic; (ii) our ability to maintain operations to support our customers and patients in the near-term and to capitalize on future growth opportunities; (iii) risks associated with acceptance of surgical products and procedures by surgeons and hospitals, (iv) development and acceptance of new products or product enhancements, (v) clinical and statistical verification of the benefits achieved via the use of our products, (vi) our ability to adequately manage inventory, (vii) our ability to recruit and retain management and key personnel, and (viii) the other risks and uncertainties more fully described in our periodic filings with the Securities and Exchange Commission (the "SEC"). To the extent that the COVID-19 pandemic continues to adversely affect our business and financial results, it may also have the effect of heightening many of the other risks described in Part I, Item 1A under the heading Risk Factors in our 2020 Form 10-K, such as our ability to generate sufficient cash flows to run our business and our ability to protect our information technology networks and infrastructure from unauthorized access, misuse, malware, phishing and other events that could have a security impact as a result of our remote working environment or otherwise. As a result of these various risks, our actual outcomes and results may differ materially from those expressed in these forward-looking statements.

This list of risks, uncertainties and other factors is not complete. We discuss some of these matters more fully, as well as certain risk factors that could affect our business, financial condition, results of operations, and prospects, in reports we file from time-to-time with the SEC, which are available to read at www.sec.gov. Any or all forward-looking statements that we make may turn out to be wrong (due to inaccurate assumptions that we make or otherwise), and our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to update, and expressly disclaim any duty to update, our forward-looking statements, whether as a result of circumstances or events that arise after the date hereof, new information, or otherwise.

ORTHOFIX MEDICAL INC. Condensed Consolidated Statements of Operations

		Three Mor Decem			Year Ended December 31,				
(U.S. Dollars, in thousands, except share and per share data)		2020		2019	2020			2019	
		(unau	dited	d)					
Net sales	\$	117,619	\$	121,494	\$	406,562	\$	459,955	
Cost of sales		29,071		26,191		101,889		100,607	
Gross profit		88,548		95,303		304,673		359,348	
Sales and marketing		53,716		58,313		204,434		223,676	
General and administrative		18,495		22,110		67,948		85,607	
Research and development		10,365		8,446		39,056		34,637	
Acquisition-related amortization and remeasurement		2,267		2,339		(499)		34,212	
Operating income (loss)		3,705		4,095		(6,266)		(18,784)	
Interest expense, net		(428)		(508)		(2,483)		(122)	
Other income (expense), net		2,293		643		8,381		(8,143)	
Income (loss) before income taxes		5,570		4,230		(368)		(27,049)	
Income tax benefit (expense)		(14,948)		7,456		2,885		(1,413)	
Net income (loss)	\$	(9,378)	\$	11,686	\$	2,517	\$	(28,462)	
Net income (loss) per common share:									
Basic	\$	(0.48)	\$	0.61	\$	0.13	\$	(1.51)	
Diluted		(0.48)		0.60		0.13		(1.51)	
Weighted average number of common shares:									
Basic		19,418,550		19,068,067		19,267,920		18,903,289	
Diluted		19,418,550		19,315,836		19,391,718		18,903,289	

ORTHOFIX MEDICAL INC. Condensed Consolidated Balance Sheets

.S. Dollars, in thousands, except share data)		ember 31, 2020	December 31, 2019		
Accets					
Assets					
Current assets	+	06 204	+	60.740	
Cash and cash equivalents	\$	96,291	\$	69,719	
Restricted cash		530 72,423		684	
Accounts receivable, net of allowances of \$4,848 and \$3,987, respectively Inventories		72,423 84,635		86,805 82,397	
Prepaid expenses and other current assets		16.500		20,948	
Total current assets		270,379		260,553	
Property, plant and equipment, net		63,613		62,727	
Intangible assets, net		60,517		54,139	
Goodwill		84,018		71,177	
Deferred income taxes		25,042		35,117	
Other long-term assets		22,292		11,907	
Total assets	\$	525,861	\$	495,620	
Liabilities and shareholders' equity					
Current liabilities					
Accounts payable	\$	23,118	\$	19,886	
Current portion of finance lease liability		510		323	
Other current liabilities		80,271		64,674	
Total current liabilities		103,899		84,883	
Long-term portion of finance lease liability		22,338		20,648	
Other long-term liabilities		42,760		62,458	
Total liabilities		168,997		167,989	
Contingencies					
Shareholders' equity					
Common shares \$0.10 par value; 50,000,000 shares authorized; 19,423,874 and 19,022,619 issued					
and outstanding as of December 31, 2020 and 2019, respectively		1,942		1,902	
Additional paid-in capital Retained earnings		292,291 59,379		271,019 57,749	

Accumulated other comprehensive income (loss)	3,252	(3,039)
Total shareholders' equity	356,864	327,631
Total liabilities and shareholders' equity	\$ 525,861	\$ 495,620

ORTHOFIX MEDICAL INC. Non-GAAP Financial Measures

The following tables present reconciliations of operating income (loss), net income (loss), EPS, and net cash from operating activities, in each case calculated in accordance with U.S. generally accepted accounting principles ("GAAP"), to, as applicable, non-GAAP financial measures, referred to as "EBITDA," "Adjusted EBITDA," "Adjusted net income," "Adjusted EPS," and "Free cash flow" that exclude items specified in the tables. A more detailed explanation of the items excluded from these non-GAAP financial measures, as well as why management believes the non-GAAP financial measures are useful to them, is included following the reconciliations.

EBITDA and Adjusted EBITDA

Three Months Ended December 31, 2020

			Global				
(Unaudited, U.S. Dollars, in thousands)	Global Spine		Extremities	Corporate	Total Orthofix		
Operating income (loss)	\$	19,386	\$ (5,151)	\$ (10,530)	\$	3,705	
Other income (expense), net		664	1,278	351		2,293	
Depreciation and amortization		2,532	2,429	1,056		6,017	
Amortization of acquired intangibles		1,784	446	_		2,230	
EBITDA	\$	24,366	\$ (998)	\$ (9,123)	\$	14,245	
Share-based compensation		1,495	498	1,816		3,809	
Foreign exchange impact		(575)	(1,197)	(349)		(2,121)	
Strategic investments		_	1,246	1,686		2,932	
Acquisition-related fair value adjustments		300	52	_		352	
Loss on investment securities		_	_	_		_	
Legal judgments/settlements		224	95	86		405	
Succession and transition charges		5	187	(3)		189	
Medical device regulation		35	744	1,366		2,145	
Business interruption - COVID-19		14	61	27		102	
Adjusted EBITDA	\$	25,864	\$ 688	\$ (4,494)	\$	22,058	

Year Ended December 31, 2020

	rear Eriaed December 51/ 2020								
	Global								
(Unaudited, U.S. Dollars, in thousands)	Global Spine			Extremities		Corporate	To	otal Orthofix	
Operating income (loss)	\$	43,265	\$	(14,917)	\$	(34,614)	\$	(6,266)	
Other income (expense), net		1,409		2,028		4,944		8,381	
Depreciation and amortization		12,091		6,580		4,288		22,959	
Amortization of acquired intangibles		6,271		1,316				7,587	
EBITDA	\$	63,036	\$	(4,993)	\$	(25,382)	\$	32,661	
Share-based compensation		6,081		2,076		7,107		15,264	
Foreign exchange impact		(1,287)		(2,099)		(510)		(3,896)	
Strategic investments		30		1,719		3,052		4,801	
Acquisition-related fair value adjustments		(7,300)		152		_		(7,148)	
Loss on investment securities		_		_		219		219	
Legal judgments/settlements		(196)		641		458		903	
Succession and transition charges		2,027		1,589		759		4,375	
Medical device regulation		411		1,240		2,333		3,984	
Business interruption - COVID 19		403		369		(4,308)		(3,536)	

Adjusted EBITDA \$ 63,205 \$ 694 \$ (16,272) \$ 47,627

Three Months Ended December 31, 2019

(Unaudited, U.S. Dollars, in thousands)	Global Spine		Extremities			Corporate	Т	otal Orthofix
Operating income (loss)	\$	14,257	\$	1,823	\$	(11,985)	\$	4,095
Other income (expense), net		476		270		(104)		642
Depreciation and amortization		2,391		1,597		1,192		5,180
Amortization of acquired intangibles		1,339				_		1,339
EBITDA	\$	18,463	\$	3,690	\$	(10,897)	\$	11,256
Share-based compensation		1,000		591		1,734		3,325
Foreign exchange impact		(438)		(311)		(4)		(753)
Strategic investments		17		_		454		471
Acquisition-related fair value adjustments		1,000		_		_		1,000
Loss on investment securities		_		_		_		_
Legal judgments/settlements		1,515		468		6		1,989
Succession and transition charges		719		_		4,168		4,887
Medical device regulation		445		84		(175)		354
Adjusted EBITDA	\$	22,721	\$	4,522	\$	(4,714)	\$	22,529

Year Ended December 31, 2019

	real Ended December 31, 2019									
	•									
(Unaudited, U.S. Dollars, in thousands)	Global Spine			Extremities		Corporate	Т	otal Orthofix		
Operating income (loss)	\$	25,722	\$	2,872	\$	(47,378)	\$	(18,784)		
Other income (expense), net		(523)		(951)		(6,670)		(8,144)		
Depreciation and amortization		9,257		5,575		4,795		19,627		
Amortization of acquired intangibles		5,072				_		5,072		
EBITDA	\$	39,528	\$	7,496	\$	(49,253)	\$	(2,229)		
Share-based compensation		5,604		2,290		7,921		15,815		
Foreign exchange impact		563		834		37		1,434		
Strategic investments		1,420		_		8,065		9,485		
Acquisition-related fair value adjustments		29,849		_		_		29,849		
Loss on investment securities		_		_		6,534		6,534		
Legal judgments/settlements		1,017		1,507		29		2,553		
Succession and transition charges		1,608		_		9,719		11,327		
Medical device regulation		712		234		7		953		
Adjusted EBITDA	\$	80,301	\$	12,361	\$	(16,941)	\$	75,721		

Adjusted Net Income

	 Three Mor Decem		Year Ended December 31,				
(Unaudited, U.S. Dollars, in thousands)	2020	2019		2020		2019	
Net income (loss)	\$ (9,378)	\$ 11,686	\$	2,517	\$	(28,462)	
Foreign exchange impact	(2,121)	(753)		(3,896)		1,434	
Strategic investments	2,947	471		4,816		9,485	
Acquisition-related fair value adjustments	352	1,000		(7,148)		29,849	
Amortization of acquired intangibles	2,231	1,339		7,587		5,072	
Interest and loss on investment securities	_	_		219		5,328	
Legal judgments/settlements	405	1,989		903		2,553	
Succession and transition charges	189	4,887		4,375		11,327	

Medical device regulation	2,145	354	3,984	953
Business interruption - COVID-19	103	_	(3,532)	_
Long-term income tax rate adjustment	11,756	(11,106)	(4,760)	(9,104)
Adjusted net income	\$ 8,629	\$ 9,867	\$ 5.065	\$ 28,435

Adjusted EPS

	 Three Months Ended December 31,			Year Ended December 31,			
(Unaudited, per diluted share)	2020		2019		2020		2019
EPS	\$ (0.48)	\$	0.60	\$	0.13	\$	(1.51)
Foreign exchange impact	(0.11)		(0.04)		(0.20)		0.07
Strategic investments	0.15		0.02		0.25		0.49
Acquisition-related fair value adjustments	0.02		0.05		(0.37)		1.58
Amortization of acquired intangibles	0.11		0.07		0.39		0.26
Interest and loss on investment securities	_		_		0.01		0.28
Legal judgments/settlements	0.02		0.10		0.05		0.13
Succession and transition charges	0.01		0.25		0.23		0.59
Medical device regulation	0.11		0.02		0.21		0.05
Business interruption - COVID-19	0.01		_		(0.18)		_
Long-term income tax rate adjustment	0.60		(0.56)		(0.26)		(0.47)
Adjusted EPS	\$ 0.44	\$	0.51	\$	0.26	\$	1.47
Weighted average number of diluted common shares (treasury stock method)	19,611,127		19,341,552		19,404,524		19,303,457

Free Cash Flow

	Year Ended December 31,							
(Unaudited, U.S. Dollars, in thousands)		2020		2019				
Net cash from operating activities	\$	74,272	\$	32,033				
Capital expenditures		(17,094)		(20,524)				
Free cash flow	\$	57,178	\$	11,509				

Constant Currency

Constant currency is a non-GAAP measure, which is calculated by using foreign currency rates from the comparable, prior-year period, to present net sales at comparable rates. Constant currency can be presented for numerous GAAP measures, but is most commonly used by management to analyze net sales without the impact of changes in foreign currency rates.

EBITDA

EBITDA is a non-GAAP financial measure, which is calculated by adding interest income (expense), net; income tax expense (benefit); and depreciation and amortization to net income. EBITDA provides management with additional insight to its results of operations. EBITDA is the primary metric used by our Chief Operating Decision Maker in

managing our business.

Adjusted EBITDA, Adjusted Net Income and Adjusted EPS

These non-GAAP financial measures provide management with additional insight to its results of operations and are calculated using the following adjustments:

- Share-based compensation costs related to our share-based compensation plans, which include stock
 options, restricted stock, market-based restricted stock awards and our stock purchase plan; see the sharebased compensation footnote in our Form 10-K for the year ended December 31, 2020 for an allocation of
 these costs by consolidated statement of income line item; note that certain share-based compensation costs
 are instead included within succession and transition charges for 2020 and 2019
- Foreign exchange impact gains and losses related to foreign currency transactions, which are recorded as other income (expense), net
- Strategic investments costs related to our strategic investments, such as due diligence and integration costs, or costs associated with the evaluation and completion of changing the Company's jurisdiction of organization from Curacao to the State of Delaware, which are primarily recorded as general and administrative expenses
- Acquisition-related fair value adjustments comprised of i) gains and losses related to remeasurement of
 contingent consideration to fair value, which are recorded as operating expenses and ii) the amortization of
 an adjustment made to inventory acquired to reflect the expected selling price of the acquired inventory less
 the cost of expected selling efforts and a reasonable profit allowance for the selling effort for finished goods
 inventory, which is recorded as cost of sales

Also included in this line are adjustments totaling \$0.03 per share in the presentation of Adjusted EPS to account for the difference in the weighted average number of shares outstanding for GAAP and Non-GAAP reporting purposes due to our reported net loss position under GAAP and net income position under Non-GAAP for the year ended December 31, 2019, as these charges were the primary driver of our net loss position

- Amortization of acquired intangibles amortization of intangible assets acquired in business combinations or asset acquisitions, including items such as developed technologies, customer relationships, trade names, manufacturing agreements, and other intangible assets, which are recorded in cost of sales or operating expenses
- Interest and loss on investment securities net gains or losses recognized (realized or unrealized) within other income (expense), net or interest income recognized relating to our investments in eNeura Inc. and Bone Biologics, Inc.
- Legal judgments/settlements adverse or favorable legal judgments or negotiated legal settlements, which are recorded as general and administrative expenses
- Succession and transition charges costs related to the transition of certain named executive officers and

- certain targeted restructuring costs, including any cessation and onboarding amounts, accelerated sharebased compensation expense, consulting services, and other related expenses, which are primarily recorded as general and administrative expenses
- Medical device regulation incremental costs incurred (i) to establish initial compliance with the regulations set forth by the European Union Medical Device Regulation ("MDR") and the U.S. Food and Drug Administration related to our currently-approved medical devices; the new European Union MDR provides a transition period until May 2021 for currently-approved medical devices, which are recorded primarily as research and development expenses, and (ii) related to rationalization of certain product lines that we do not expect to continue to market subsequent to the effective date of these regulations, which are recorded primarily as costs of sales
- Business interruption COVID-19 gains and losses related to the realized effects the COVID-19 pandemic has had on our business operations, which consist primarily of i) certain proceeds received as part of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which are recognized in other income (expense), net, ii) inventory reserve adjustments related to product set to expire, which are reflected in cost of sales, and iii) incremental costs incurred to enhance the safety and sanitation of our facilities in response to COVID-19, which are primarily reported in general and administrative expenses
- Long-term income tax rate adjustment reflects management's expectation of a long-term normalized effective tax rate of 27% for 2019 and 2020 results and for the fiscal year 2021 outlook, which is based on current tax law and current expected adjusted income; actual reported tax expense will ultimately be based on GAAP earnings and may differ from the expected long-term normalized effective tax rate due to a variety of factors, including the resolutions of issues arising from tax audits with various tax authorities, the ability to realize deferred tax assets, and the tax impact of certain reconciling items that are excluded in determining Adjusted Net Income and Adjusted EPS

Free Cash Flow

Free cash flow is a non-GAAP financial measure, which is calculated by subtracting capital expenditures from cash flow from operating activities. Free cash flow is an important indicator of how much cash is generated or used by our normal business operations, including capital expenditures. Management uses free cash flow as a measure of progress on its capital efficiency and cash flow initiatives.

Usefulness and Limitations of Non-GAAP Financial Measures

Management uses non-GAAP measures to evaluate performance period-over-period, to analyze the underlying trends in our business, to assess performance relative to competitors and to establish operational goals and forecasts that are used in allocating resources. Management uses these non-GAAP measures as the basis for assessing the ability of the underlying operations to generate cash. In addition, management uses these non-GAAP measures to further its understanding of the performance of our business units.

Material Limitations Associated with the Use of Non-GAAP Financial Measures

The non-GAAP measures used in this press release may have limitations as analytical tools, and should not be considered in isolation or as a replacement for GAAP financial measures. Some of the limitations associated with the use of these non-GAAP financial measures are that they exclude items that reflect an economic cost and can

have a material effect on cash flows. Similarly, certain non-cash expenses, such as equity compensation, do not

directly impact cash flows, but are part of total compensation costs accounted for under GAAP.

Compensation for Limitations Associated with Use of Non-GAAP Financial Measures

We compensate for the limitations of our non-GAAP financial measures by relying upon GAAP results to gain a

complete picture of our performance. The GAAP results provide the ability to understand our performance based

on a defined set of criteria. The non-GAAP measures reflect the underlying operating results of our businesses,

which we believe is an important measure of our overall performance. We provide a detailed reconciliation of the

non-GAAP financial measures to our most directly comparable GAAP measures, and encourage investors to review

this reconciliation.

Usefulness of Non-GAAP Financial Measures to Investors

We believe that providing non-GAAP financial measures that exclude certain items provides investors with greater

transparency to the information used by senior management in its financial and operational decision-making.

Management believes it is important to provide investors with the same non-GAAP metrics it uses to supplement

information regarding the performance and underlying trends of our business operations in order to facilitate

comparisons to its historical operating results and internally evaluate the effectiveness of our operating strategies.

Disclosure of these non-GAAP financial measures also facilitates comparisons of our underlying operating

performance with other companies in the industry that also supplement their GAAP results with non-GAAP financial

measures.

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