

NEWS RELEASE

Orthofix Reports Second Quarter 2022 Results

8/5/2022

- Net sales of \$118.1 million, a decrease of 3% on a reported basis and flat on a constant currency basis over prior year
- Global Orthopedics net sales growth of 11% on a constant currency basis driven by new products and channel investments
- GAAP EPS of \$0.12 and adjusted EPS of \$0.08
- Executed partnership with CGBio to commercialize Novosis™ rhBMP-2 growth factor in the U.S. and Canada
- Limited launch of Virtuos™ Lyograft, a first-of-its-kind, shelf-stable and complete autograft substitute
- Full year revenue guidance of \$455 to \$465, which represents flat to 2% growth on a constant currency basis over prior year

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix Medical Inc. (NASDAQ:OFIX) today reported its financial results for the quarter ended June 30, 2022. Net sales were \$118.1 million, earnings per share ("EPS") was \$0.12, and adjusted EPS was \$0.08.

"We're pleased with our execution in the second quarter, which was led by double digit growth in our global orthopedic business as well as early commercial traction of new spine products. In addition, we made significant progress on our innovation initiatives, highlighted by the successful launches of the AccelStim™ Bone Healing Therapy and Virtuos Lyograft, as well as our recent partnerships with LimaCorporate and CGBio," said Orthofix President and Chief Executive Officer Jon Serbousek. "We had solid operational execution, despite the challenges that macro headwinds continue to present, including continued hospital staffing shortages, complex spine procedure softness, and patients deferring care due to economic pressures. In addition, currency fluctuations during the quarter dampened reported revenue results."

Continued Serbousek, "We remain incredibly bullish on the long-term opportunity here at Orthofix. While the macro environment is causing near-term volatility, we are fully committed to driving accelerated topline growth in the high single digits and continuing to execute towards increasing profitability. With the strength of our balance sheet as well as organic and inorganic investments made throughout the organization, we will work to continue to drive growth over the near term from key new product launches and channel expansion."

Financial Results Overview

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

Three Mor	nths En	ded Iu	ıne 30.
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		0004		Constant Currency
(Unaudited, U.S. Dollars, in thousands)	2022	2021	Change	Change
Bone Growth Therapies	\$ 47,765	\$ 49,706	(3.9%)	(3.9%)
Spinal Implants	28,222	30,092	(6.2%)	(5.4%)
Biologics	14,795	14,852	(0.4%)	(0.4%)
Global Spine	90,782	94,650	(4.1%)	(3.8%)
Global Orthopedics	27,288	26,744	2.0%	11.4%
Net sales	\$ 118,070	\$ 121,394	(2.7%)	(0.5%)

Gross profit decreased \$7.5 million to \$86.5 million. Gross margin decreased to 73.2% compared to 77.4% in the prior year period.

Net income was \$2.5 million, or \$0.12 per share, compared to net income of \$2.4 million, or \$0.12 per share in the prior year period. Adjusted net income was \$1.5 million, or \$0.08 per share, compared to adjusted net income of \$6.3 million, or \$0.32 per share in the prior year period.

EBITDA was \$10.0 million, compared to \$12.8 million in the prior year period. Adjusted EBITDA was \$11.4 million, or 9.7% of net sales, compared to \$18.4 million, or 15.1% of net sales, in the prior year period.

Liquidity

As of June 30, 2022, cash and cash equivalents totaled \$59.5 million, compared to \$87.8 million as of December 31, 2021. As of June 30, 2022, the Company had no borrowings under its five year \$300 million secured revolving credit facility. Cash flow from operations decreased \$12.9 million to \$(12.6) million, while free cash flow decreased \$14.8 million to \$(24.3) million.

CGBio Exclusive Recombinant Bone Growth Protein Partnership

On August 2, 2022, we announced our new long-term strategic license and distribution agreement with CGBio, a developer of innovative, synthetic bone grafts currently approved and commercially available in South Korea, Southeast Asia, Mexico, and India. The agreement grants us the exclusive right to conduct pre-clinical and clinical studies, commercialize, promote, market, and sell the Novosis (rhBMP-2) recombinant bone growth protein in the U.S. and Canada. Novosis is a novel composite bone graft material that is flowable and provides moldable handling characteristics that are unique compared to what is currently on the market in the U.S. and Canada and represents the next evolution of bone growth factor technology.

Business Outlook

As of the date hereof, the Company expects the following net sales results for the year ended December 31, 2022. These expectations are based on the current foreign currency exchange rates and do not include any additional exchange rate changes that may occur this year.

	Current 2022 Outlook	Previous 2022 Outlook
(Unaudited, U.S. Dollars, in millions, except per share data)	Range	Range
Full year net sales	\$455 - \$465	\$475 - \$490
Full year net sales growth rates – reported	(2%) - 0%	2% - 5%
Full year net sales growth rates – constant currency	0% - 2%	4% - 7%
Full year adjusted EBITDA	\$53 - \$57	\$56 - \$61
Full year adjusted EBITDA as percentage of net sales 1	12%	12% - 13%
Full year adjusted EPS	\$0.45-\$0.55	\$0.58-\$0.73

¹ Calculated using the midpoint of estimated full year net sales

The Company is not able to provide expectations of operating income or GAAP EPS, the closest comparable U.S. GAAP measures to Adjusted EBITDA and Adjusted EPS, respectively (each of which are non-GAAP measures), on a forward-looking basis because the Company is unable to predict without unreasonable efforts the ultimate outcome of matters (including legal proceedings, acquisition-related expenses, accounting fair value adjustments, and other such items) that will determine the quantitative amount of the items excluded from the applicable non-GAAP measure, which items are further described in the reconciliation tables and related descriptions below. 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 second quarter of 2022. Interested parties may access the conference call by dialing (844) 200-6205 in the U.S. and Canada, and (929) 526-1599 all other locations, and referencing the access code 135199. A replay of the call will be available for three weeks by dialing (866) 813-9403 in the U.S. and Canada, and (929) 458-6194 in all other locations, and entering the access code 312854. A webcast of the conference call may be accessed at **ir.Orthofix.com**.

About Orthofix

Orthofix Medical Inc. is a global medical device company with a spine and orthopedics focus. The Company's mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, Orthofix's spine and orthopedics products are distributed in

more than 60 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, 2021 (the "2021 Form 10-K"), and in Part II, Item 1A under the heading Risk Factors in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022. 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, (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, (viii) global economic instability and potential supply chain disruption caused by Russia's unlawful invasion of Ukraine and resulting sanctions, and (ix) 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 2021 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

Condensed Consolidated Sta	d Statements of Operations_								
	TI	hree Mor	nths E	Ended	Six Months Ended				
		June	e 30,			Jur	ne 30,		
(U.S. Dollars, in thousands, except share and per share data)	:	2022		2021		2022		2021	
		(Unaudited)				(Una	audited)		
Net sales	\$	118,070	\$	121,394	\$	224,488	\$	226,987	
Cost of sales		31,600		27,439		59,918		53,353	
Gross profit		86,470		93,955		164,570		173,634	
Sales and marketing		59,888		57,338		114,025		108,123	
General and administrative		15,846		18,335		35,174		34,779	
Research and development		12,758		13,121		23,970		24,018	
Acquisition-related amortization and remeasurement		(8,663)		894		(12,162)		5,363	
Operating income		6,641		4,267		3,563		1,351	
Interest expense, net		(407)		(550)		(782)		(967)	
Other income (expense), net		(3,192)		951		(4,128)		(1,739)	
Income (loss) before income taxes		3,042		4,668		(1,347)		(1,355)	
Income tax expense		(553)		(2,248)		(624)		(2,041)	
Net income (loss)	\$	2,489	\$	2,420	\$	(1,971)	\$	(3,396)	
Net income (loss) per common share:									
Basic	\$	0.12	\$	0.12	\$	(0.10)	\$	(0.17)	
Diluted		0.12		0.12		(0.10)		(0.17)	
Weighted average number of common shares (in millions):									
Basic		20.0		19.7		20.0		19.6	
Diluted		20.1		19.9		20.0		19.6	

ORTHOFIX MEDICAL INC. Condensed Consolidated Balance Sheets

		June 30,	December 31,		
(U.S. Dollars, in thousands, except par value data)		2022	2021		
	(Unaudited)			
Assets					
Current assets					
Cash and cash equivalents	\$	59,536	\$	87,847	
Accounts receivable, net of allowances of \$5,589 and \$4,944, respectively		77,069		78,560	
Inventories		97,171		82,974	
Prepaid expenses and other current assets		21,416		20,141	
Total current assets		255,192		269,522	
Property, plant, and equipment, net		58,676		59,252	
Intangible assets, net		50,634		52,666	
Goodwill		71,317		71,317	
Deferred income taxes		1,454		1,771	
Other long-term assets		24,383		22,095	
Total assets	\$	461,656	\$	476,623	
Liabilities and shareholders' equity					
Current liabilities					
Accounts payable	\$	32,322	\$	26,459	
Current portion of finance lease liability		624		2,590	
Other current liabilities		48,151		76,781	
Total current liabilities		81,097		105,830	
Long-term portion of finance lease liability		19,571		19,890	
Other long-term liabilities		19,042		13,969	
Total liabilities		119,710		139,689	

Contingencies		
Shareholders' equity		
Common shares \$0.10 par value; 50,000 shares authorized;		
20,000 and 19,837 issued and outstanding as of June 30,		
2022 and December 31, 2021, respectively	2,000	1,983
Additional paid-in capital	323,738	313,951
Retained earnings	19,029	21,000
Accumulated other comprehensive loss	(2,821)	
Total shareholders' equity	341,946	336,934
Total liabilities and shareholders' equity	\$ 461,656	\$ 476,623

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 (loss)," "Adjusted EPS," and "Free cash flow" that exclude items specified in the tables. The GAAP measures shown in the tables below represent the most comparable GAAP measure to the applicable non-GAAP measure(s) shown in the table. 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. The non-GAAP adjusted results shown below and within this press release, which exclude the items specified in the reconciliation tables below, should not be construed as a substitute for, or a better indicator of, the Company's performance than the Company's GAAP results.

EBITDA and Adjusted EBITDA

Three Months Ended June 30, 2022

(Unaudited, U.S. Dollars, in		Total	Global						
thousands)	0	rthofix	Glob	Global Spine Orthopedics		hopedics	Corporate		
Operating income (loss)	\$	6,641	\$	17,551	\$	(2,290)	\$	(8,620)	
Other income (expense), net		(3,192)		(810)		(1,736)		(646)	
Depreciation and amortization		4,461		2,137		1,441		883	
Amortization of acquired intangibles		2,051		1,888		163		_	
EBITDA	\$	9,961	\$	20,766	\$	(2,422)	\$	(8,383)	
Share-based compensation		4,449		1,957		252		2,240	
Foreign exchange impact		2,991		664		1,801		526	
Strategic investments		1,824		39		270		1,515	
Acquisition-related fair value									
adjustments		(10,714)		(10,714)		_		_	
Loss on investment securities		123		_		_		123	
Legal judgments/settlements		148		110		39		(1)	
Succession and transition charges		68		44		7		17	
Medical device regulation		2,257		1,431		830		(4)	
Business interruption - COVID-19		316		313		3		_	
Adjusted EBITDA	\$	11,423	\$	14,610	\$	780	\$	(3,967)	
As a % of net sales		9.7%		12.4%		0.7%		-3.4%	

Six Months Ended June 30, 2022

(Unaudited, U.S. Dollars, in		Total	Global						
thousands)	0	rthofix	Glob	oal Spine		hopedics	Corporate		
Operating income (loss)	\$	3,563	\$	28,918	\$	(6,562)	\$	(18,793)	
Other income (expense), net		(4,128)		(735)		(2,477)		(916)	
Depreciation and amortization		9,752		4,759		2,962		2,031	
Amortization of acquired intangibles		4,276		3,717		559			
EBITDA	\$	13,463	\$	36,659	\$	(5,518)	\$	(17,678)	
Share-based compensation		8,697		3,411		853		4,433	
Foreign exchange impact		4,233		1,037		2,512		684	
Strategic investments		2,794		102		415		2,277	
Acquisition-related fair value									
adjustments		(16,214)		(16,214)		_		_	
Loss on investment securities		188		_		_		188	
Legal judgments/settlements		341		116		223		2	
Succession and transition charges		78		54		7		17	
Medical device regulation		4,293		2,837		1,466		(10)	
Business interruption - COVID-19		659		641		18			
Adjusted EBITDA	\$	18,532	\$	28,643	\$	(24)	\$	(10,087)	
As a % of net sales		8.3%		12.8%	•	0.0%	·	-4.5%	

Three Months Ended June 30, 2021

(Unaudited, U.S. Dollars, in		Total	Global							
thousands)	0	rthofix	Glok	Global Spine Orthopedics				Corporate		
Operating income (loss)	\$	4,267	\$	14,212	\$	(1,037)	\$	(8,908)		
Other income (expense), net		951		398		645		(92)		
Depreciation and amortization		5,324		2,638		1,716		970		
Amortization of acquired intangibles		2,235		1,784		451		_		
EBITDA	\$	12,777	\$	19,032	\$	1,775	\$	(8,030)		
Share-based compensation		3,900		1,618		606		1,676		
Foreign exchange impact		(1,061)		(378)		(775)		92		
Strategic investments		1,150		152		634		364		
Acquisition-related fair value										
adjustments		(1,089)		(714)		_		(375)		
Legal judgments/settlements		61		1		59		1		
Succession and transition charges		613		392		62		159		
Medical device regulation		1,987		602		559		826		
Business interruption - COVID-19		26		4		10		12		
Adjusted EBITDA	\$	18,364	\$	20,709	\$	2,930	\$	(5,275)		
As a % of net sales		15.1%		17.1%		2.4%		-4.3%		

Six Months Ended June 30, 2021

		SIX World S Eriaca Jane 30, 2021									
	⁻ otal	Global									
Or	thofix	Glob	oal Spine	Ort	hopedics	Corporate					
\$	1,351	\$	22,324	\$	(3,899)	\$	(17,074)				
	(1,739)		(218)		(793)		(728)				
	10,532		5,252		3,337		1,943				
	4,470		3,569		901						
\$	14,614	\$	30,927	\$	(454)	\$	(15,859)				
	7,621		3,126		1,132		3,363				
	1,601		246		626		729				
	2,561		152		1,734		675				
	1,475		1,850		_		(375)				
	2		(50)		105		(53)				
	643		422		62		159				
	3,811		1,105		1,066		1,640				
	47		6		16		25				
		(1,739) 10,532 4,470 \$ 14,614 7,621 1,601 2,561 1,475 2 643 3,811	Total Orthofix \$ 1,351	Total Orthofix Global Spine \$ 1,351 \$ 22,324 (1,739) (218) 10,532 \$ 5,252 4,470 \$ 3,569 \$ 14,614 \$ 30,927 7,621 \$ 3,126 1,601 \$ 246 2,561 \$ 152 1,475 \$ 1,850 2 (50) 643 \$ 422 3,811 \$ 1,105	Total Orthofix \$ 1,351	Total Orthofix Global Spine Global Orthopedics \$ 1,351 \$ 22,324 \$ (3,899) (1,739) (218) (793) 10,532 5,252 3,337 4,470 3,569 901 \$ 14,614 \$ 30,927 \$ (454) 7,621 3,126 1,132 1,601 246 626 2,561 152 1,734 1,475 1,850 — 2 (50) 105 643 422 62 3,811 1,105 1,066	Total Orthofix Global Spine Orthopedics Co \$ 1,351 \$ 22,324 \$ (3,899) \$ (1,739) \$ (1,739) (218) (793) \$ 10,532 5,252 3,337 \$ 4,470 3,569 901 \$ 14,614 \$ 30,927 \$ (454) \$ (454) \$ 7,621 3,126 1,132 \$ 1,601 246 626 \$ 2,561 152 1,734 \$ 1,475 1,850 — \$ 2 (50) 105 643 422 62 3,811 1,105 1,066				

Adjusted EBITDA	\$ 32,375	\$ 37,784	\$ 4,287	\$ (9,696)
As a % of net sales	14.3%	16.6%	1.9%	-4.3%

Adjusted Net Income (Loss)

	Three Months Ended June 30,					Six Months Ended June 30,			
(Unaudited, U.S. Dollars, in thousands)		2022		2021		2022	2021		
Net income (loss)	\$	2,489	\$	2,420	\$	(1,971)	\$ (3,396)		
Foreign exchange impact		2,991		(1,061)		4,233	1,601		
Strategic investments		1,817		1,181		2,782	2,633		
Acquisition-related fair value adjustments		(10,714)		(1,089)		(16,214)	1,475		
Amortization of acquired intangibles		2,051		2,242		4,282	4,481		
Loss on investment securities		123		_		188	_		
Legal judgments/settlements		148		61		341	2		
Succession and transition charges		68		613		78	643		
Medical device regulation		2,260		1,987		4,296	3,811		
Business interruption - COVID-19		318		28		663	51		
Long-term income tax rate adjustment		(37)		(82)		819	(1,562)		
Adjusted net income (loss)	\$	1,514	\$	6,300	\$	(503)	\$ 9,739		

Adjusted EPS

	Three Months Ended				Six Months Ended				
	June 30,				June 30,				
(Unaudited, per diluted share)		2022		2021		2022		2021	
EPS	\$	0.12	\$	0.12	\$	(0.10)	\$	(0.17)	
Foreign exchange impact		0.15		(0.05)		0.21		0.08	
Strategic investments		0.09		0.06		0.14		0.13	
Acquisition-related fair value adjustments		(0.53)		(0.05)		(0.81)		0.08	
Amortization of acquired intangibles		0.10		0.11		0.21		0.22	
Loss on investment securities		0.01		_		0.01		_	
Legal judgments/settlements		0.01		_		0.02		_	
Succession and transition charges		_		0.03		_		0.03	
Medical device regulation		0.11		0.10		0.22		0.19	
Business interruption - COVID-19		0.02		_		0.03		_	
Long-term income tax rate adjustment		_		_		0.04		(0.07)	
Adjusted EPS	\$	0.08	\$	0.32	\$	(0.03)	\$	0.49	
							-		
Weighted average number of diluted common shares									
(treasury stock method, in millions)		20.1		20.0		20.0		19.9	

Cash Flow and Free Cash Flow

	Six Months Ended June 30			
(Unaudited, U.S. Dollars, in thousands)		2022		2021
Net cash from operating activities	\$	(12,622)	\$	264
Net cash from investing activities		(13,161)		(9,792)
Net cash from financing activities		(1,324)		(6,528)
Effect of exchange rate changes on cash		(1,204)		(243)
Net change in cash and cash equivalents	\$	(28,311)	\$	(16,299)

	Six Months Ended June 30,					
(Unaudited, U.S. Dollars, in thousands)	2022			2021		
Net cash from operating activities	\$	(12,622)	\$	264		
Capital expenditures		(11,70 <u>3</u>)		(9,792)		
Free cash flow	\$	(24,325)	\$	(9,528)		

Constant Currency

Constant currency is a non-GAAP measure, which we calculate 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 we calculate 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 (Loss) and Adjusted EPS

These non-GAAP financial measures provide management with additional insight to its results of operations and reflect the exclusion of the following items:

- Share-based compensation expense costs related to our share-based compensation plans, which include stock options, restricted stock, performance-based or market-based restricted stock, and our stock purchase plan; see the share-based compensation footnote in our Form 10-Q for the quarter ended June 30, 2022 for an allocation of these costs by consolidated statement of operations line item; note that certain share-based compensation costs are instead included within medical device regulation for 2021 and 2022
- 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, 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) recognized costs
 related to acquired in-process research and development assets, which were expensed immediately
- 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
- Loss on investment securities net gains or losses recognized (realized or unrealized) within other income (expense), net relating to certain of our investments
- 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, 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 legislative relief received as a result of the COVID-19 pandemic, (ii) costs associated with the redesign of certain products in response to supply chain disruption, and (iii) incremental costs incurred to enhance the safety and sanitation of our facilities
- Long-term income tax rate adjustment reflects management's expectation of a long-term normalized effective tax rate of 27% for 2021 and 28% for the fiscal year 2022 results and 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 to measure 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, analyze the underlying trends in our business, assess performance relative to competitors, and establish operational goals and forecasts that are

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used in allocating resources. Management uses these non-GAAP measures as the basis for evaluating 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 financial 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 share-based 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 management with the ability to further understand our performance based on a defined set of criteria. Management believes that the non-GAAP measures reflect the underlying operating results of our businesses and provide an important measure of our overall performance. We provide detailed reconciliations of the non-GAAP financial measures to the most directly comparable GAAP measures above and encourage investors to review these reconciliations.

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 our historical operating results and internally evaluate the effectiveness of our operating strategies. We believe that 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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