



## Orthofix Reports Third Quarter 2019 Results

October 28, 2019

- **Jon Serbousek to succeed Brad Mason as President and Chief Executive Officer on November 1, 2019**
- **Net sales of \$113.5 million, an increase of 1.6% compared to prior year and 2.5% on a constant currency basis**
- **Biologics tissue services fees increased 11.4%, its second consecutive quarter of double-digit growth**
- **Company entered into a new revolving credit facility which provides up to \$300 million in borrowing capacity**
- **Company updates full year 2019 guidance**

LEWISVILLE, Texas--(BUSINESS WIRE)--Oct. 28, 2019-- Orthofix Medical Inc. (NASDAQ:OFIX) today reported its financial results for the third quarter ended September 30, 2019. Net sales were \$113.5 million, loss per share ("EPS") was (\$2.14) and adjusted EPS was \$0.41.

"While we are very pleased with the sales trajectory of the M6 cervical disc in the U.S. and the continued strong performance of Biologics tissue sales, spine leadership vacancies, the delay of several large stocking orders in Extremities and the uncertainty around the CEO transition timing negatively impacted other parts of our business in the third quarter," said Brad Mason, President and Chief Executive Officer. "The good news is that these issues are temporary and not reflective of the core value proposition at Orthofix and the opportunity for growth and shareholder value creation. Jon Serbousek hit the ground running and is fully engaged and focused on recruiting candidates for the vacant leadership positions. We expect the momentum of the M6-C disc and the experience and value that the new spine leadership team brings will have a positive impact on future performance."

### Financial Results Overview

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

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended September 30,					
	2019	2018	Change		Constant Currency Change	
Bone Growth Therapies	\$ 48,836	\$ 48,059	1.6	%	1.6	%
Spinal Implants	22,947	22,102	3.8	%	4.4	%
Biologics	16,308	14,636	11.4	%	11.4	%
Global Spine	88,091	84,797	3.9	%	4.0	%
Global Extremities	25,408	26,911	(5.6)	%	(2.4)	%
<b>Net sales</b>	<b>\$ 113,499</b>	<b>\$ 111,708</b>	<b>1.6</b>	<b>%</b>	<b>2.5</b>	<b>%</b>

Gross profit increased \$0.9 million to \$88.6 million. Gross margin decreased to 78.1% compared to 78.5% in the prior year period.

Based on the initial success observed in our launch of the M6-C artificial cervical disc in the U.S. market, our long-term forecasts of net sales now indicate a greater likelihood of achieving the potential revenue-based milestone payments associated with the Spinal Kinetics acquisition. As such, we recognized expenses during the quarter of \$22.3 million associated with the remeasurement of these potential milestone payment liabilities.

Net loss was (\$40.5) million, or (\$2.14) per share, compared to net loss of (\$1.2) million, or (\$0.07) per share in the prior year period, primarily driven by the remeasurement of the potential Spinal Kinetics milestone payment liabilities discussed above. Adjusted net income from continuing operations was \$7.9 million, or \$0.41 per share, compared to adjusted net income of \$8.3 million, or \$0.44 per share in the prior year period.

EBITDA was (\$20.8) million, compared to \$3.6 million in the prior year period, largely due to the remeasurement of the potential Spinal Kinetics milestone payment liabilities. Adjusted EBITDA was \$20.3 million, or 17.9% of net sales, compared to \$21.4 million, or 19.2% of net sales, in the prior year period.

### Liquidity

As of September 30, 2019, cash, cash equivalents, and restricted cash totaled \$57.5 million compared to \$72.2 million as of December 31, 2018. Cash flow from operations for the nine months ended September 30, 2019 decreased \$8.7 million to \$20.1 million when compared to the prior year period, while free cash flow decreased \$12.9 million to \$5.2 million.

As of September 30, 2019, the Company had no outstanding indebtedness and borrowing capacity of \$125 million under its previous credit facility. On October 25, 2019, the Company, and certain of its wholly-owned subsidiaries, entered into a Second Amended and Restated Credit Agreement (the "Amended Credit Agreement") with JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lender parties thereto. The Amended Credit Agreement provides for a \$300 million secured revolving credit facility maturing in October 2024.

## 2019 Outlook

For the year ending December 31, 2019, the Company expects the following results, including the impact of any expected changes in foreign currency exchange rates.

(Unaudited, U.S. Dollars, in millions, except per share data)	Previous 2019 Outlook		Current 2019 Outlook	
	Low	High	Low	High
Net sales	\$ 472.0	\$ 477.0	\$ 460.0 <sup>1</sup>	\$ 463.0 <sup>1</sup>
Net income (loss)	\$ 12.7	\$ 13.6	\$ (24.3 ) <sup>2</sup>	\$ (22.8 ) <sup>2</sup>
Adjusted EBITDA	\$ 86.0	\$ 89.0	\$ 78.0 <sup>3</sup>	\$ 80.0 <sup>3</sup>
EPS	\$ 0.66	\$ 0.70	\$ (1.25 ) <sup>4</sup>	\$ (1.18 ) <sup>4</sup>
Adjusted EPS	\$ 1.75	\$ 1.82	\$ 1.55 <sup>5</sup>	\$ 1.60 <sup>5</sup>

<sup>1</sup> Represents a year-over-year increase of 1.5% to 2.2% on a reported basis

<sup>2</sup> Represents a year-over-year decrease of 275.9% to 265.1%

<sup>3</sup> Represents a year-over-year decrease of 11.0% to 8.7%

<sup>4</sup> Represents a year-over-year decrease of 273.6% to 263.9%

<sup>5</sup> Represents a year-over-year decrease of 13.4% to 10.6%

## Conference Call

Orthofix will host a conference call today at 4:30 PM Eastern time to discuss the Company's financial results for the third quarter of 2019. Interested parties may access the conference call by dialing (844) 809-1992 in the U.S. and (612) 979-9886 outside the U.S., and referencing the conference ID 5592946. A replay of the call will be available for two weeks by dialing (855) 859-2056 in the U.S. and (404) 537-3406 outside the U.S., and entering the conference ID 5592946. A webcast of the conference call may be accessed by going to the Company's website at [www.orthofix.com](http://www.orthofix.com), by clicking on the Investors link and then the Events and Presentations page.

## About Orthofix

Orthofix Medical Inc. is a global medical device company focused on musculoskeletal products and therapies. The Company's mission is to improve patients' lives by providing superior reconstruction and regenerative musculoskeletal solutions to physicians worldwide. 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](http://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 ("the Exchange Act"), 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. Therefore, 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 further update any such statement, or the risk factors described in Part I, Item 1A under the heading Risk Factors in our Form 10-K for the year ended December 31, 2018, to reflect new information, the occurrence of future events or circumstances or otherwise.

## ORTHOFIX MEDICAL INC.

## Condensed Consolidated Statements of Operations

Three Months Ended

Nine Months Ended

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	September 30,		September 30,	
	2019	2018	2019	2018
Net sales	\$ 113,499	\$ 111,708	\$ 338,461	\$ 331,964
Cost of sales	24,896	24,020	74,416	71,002
Gross profit	88,603	87,688	264,045	260,962
Sales and marketing	54,805	49,898	165,363	151,695
General and administrative	21,090	22,276	63,497	63,658
Research and development	7,982	9,598	26,191	24,426
Acquisition-related amortization and remeasurement	23,608	2,009	31,873	3,491
Operating income (loss)	(18,882 )	3,907	(22,879 )	17,692
Interest income (expense), net	186	(181 )	386	(615 )
Other expense, net	(8,146 )	(5,054 )	(8,786 )	(5,785 )
Income (loss) before income taxes	(26,842 )	(1,328 )	(31,279 )	11,292
Income tax benefit (expense)	(13,656 )	117	(8,869 )	(6,352 )
<b>Net income (loss)</b>	<b>\$ (40,498 )</b>	<b>\$ (1,211 )</b>	<b>\$ (40,148 )</b>	<b>\$ 4,940</b>

Net income (loss) per common share:

Basic	\$ (2.14 )	\$ (0.07 )	\$ (2.13 )	\$ 0.26
Diluted	(2.14 )	(0.07 )	(2.13 )	0.26

Weighted average number of common shares:

Basic	18,957,876	18,562,204	18,847,728	18,460,848
Diluted	18,957,876	18,562,204	18,847,728	18,864,169

**ORTHOFIX MEDICAL INC.**

**Condensed Consolidated Balance Sheets**

(U.S. Dollars, in thousands, except share data)

September 30, December 31,  
2019 2018

(unaudited)

**Assets**

## Current assets

Cash and cash equivalents	\$ 56,849	\$ 69,623
Restricted cash	654	2,566
Trade accounts receivable, net of allowances of \$4,073 and \$7,463, respectively	79,690	77,747
Inventories	80,993	76,847
Prepaid expenses and other current assets	19,617	17,856
<b>Total current assets</b>	<b>237,803</b>	<b>244,639</b>
Property, plant and equipment, net	62,964	42,835
Intangible assets, net	53,613	51,897
Goodwill	71,177	72,401
Deferred income taxes	39,626	33,228
Other long-term assets	10,420	21,641
<b>Total assets</b>	<b>\$ 475,603</b>	<b>\$ 466,641</b>

**Liabilities and shareholders' equity**

## Current liabilities

Trade accounts payable	\$ 17,892	\$ 17,989
Current portion of finance lease liability	293	—
Other current liabilities	70,323	67,919
<b>Total current liabilities</b>	<b>88,508</b>	<b>85,908</b>
Long-term portion of finance lease liability	20,767	—
Other long-term liabilities	59,894	45,336
<b>Total liabilities</b>	<b>169,169</b>	<b>131,244</b>

## Contingencies

## Shareholders' equity

Common shares \$0.10 par value; 50,000,000 shares authorized; 18,875,184 and 18,579,688 issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1,888	1,858
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Additional paid-in capital	263,064	243,165
Retained earnings	46,063	87,078
Accumulated other comprehensive income (loss)	(4,581 )	3,296
Total shareholders' equity	306,434	335,397
<b>Total liabilities and shareholders' equity</b>	<b>\$ 475,603</b>	<b>\$ 466,641</b>

**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 September 30, 2019**

<b>(Unaudited, U.S. Dollars, in thousands)</b>	<b>Global Spine</b>	<b>Global Extremities</b>	<b>Corporate</b>	<b>Total Orthofix</b>
<b>Operating income (loss)</b>	\$ (8,961 )	\$ 691	\$ (10,612 )	\$ (18,882 )
Other income (expense), net	(775 )	(814 )	(6,557 )	(8,146 )
Depreciation and amortization	2,365	1,352	1,220	4,937
Amortization of acquired intangibles	1,338	—	—	1,338
<b>EBITDA</b>	<b>\$ (6,033 )</b>	<b>\$ 1,229</b>	<b>\$ (15,949 )</b>	<b>\$ (20,753 )</b>
Share-based compensation	1,291	566	2,280	4,137
Foreign exchange impact	776	803	18	1,597
Strategic investments	154	—	1,966	2,120
Acquisition-related fair value adjustments	22,270	—	—	22,270
Loss on investment securities	—	—	6,534	6,534
Legal judgments/settlements	2	1,312	2	1,316
Succession charges	757	—	1,683	2,440
European Union Medical Device Regulation	267	150	182	599
<b>Adjusted EBITDA</b>	<b>\$ 19,484</b>	<b>\$ 4,060</b>	<b>\$ (3,284 )</b>	<b>\$ 20,260</b>

**Nine Months Ended September 30, 2019**

<b>(Unaudited, U.S. Dollars, in thousands)</b>	<b>Global Spine</b>	<b>Global Extremities</b>	<b>Corporate</b>	<b>Total Orthofix</b>
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<b>Operating income (loss)</b>	\$ 11,465	\$ 1,049	\$ (35,393 )	\$ (22,879 )
Other income (expense), net	(999 )	(1,221 )	(6,566 )	(8,786 )
Depreciation and amortization	6,866	3,978	3,603	14,447
Amortization of acquired intangibles	3,733	—	—	3,733
<b>EBITDA</b>	<b>\$ 21,065</b>	<b>\$ 3,806</b>	<b>\$ (38,356 )</b>	<b>\$ (13,485 )</b>
Share-based compensation	4,604	1,699	6,187	12,490
Foreign exchange impact	1,001	1,145	41	2,187
Strategic investments	1,403	—	7,611	9,014
Acquisition-related fair value adjustments	28,849	—	—	28,849
Loss on investment securities	—	—	6,534	6,534
Legal judgments/settlements	(498 )	1,039	23	564
Succession charges	889	—	5,551	6,440
European Union Medical Device Regulation	267	150	182	599
<b>Adjusted EBITDA</b>	<b>\$ 57,580</b>	<b>\$ 7,839</b>	<b>\$ (12,227 )</b>	<b>\$ 53,192</b>

**Three Months Ended September 30, 2018**

<b>(Unaudited, U.S. Dollars, in thousands)</b>	<b>Global Spine</b>	<b>Global Extremities</b>	<b>Corporate</b>	<b>Total Orthofix</b>
<b>Operating income (loss)</b>	\$ 13,344	\$ 2,361	\$ (11,798 )	\$ 3,907
Other income (expense), net	(196 )	(301 )	(4,557 )	(5,054 )
Depreciation and amortization	2,060	1,297	952	4,309
Amortization of acquired intangibles	429	—	—	429
<b>EBITDA</b>	<b>\$ 15,637</b>	<b>\$ 3,357</b>	<b>\$ (15,403 )</b>	<b>\$ 3,591</b>
Share-based compensation	1,391	633	3,237	5,261
Foreign exchange impact	272	277	69	618
Strategic investments	803	—	3,001	3,804
Acquisition-related fair value adjustments	2,121	—	—	2,121
Loss on investment securities	—	—	4,449	4,449
Legal judgments/settlements	241	39	92	372

Succession charges	1,233	—	—	1,233
<b>Adjusted EBITDA</b>	<b>\$ 21,698</b>	<b>\$ 4,306</b>	<b>\$ (4,555 )</b>	<b>\$ 21,449</b>

**Nine Months Ended September 30, 2018**

<b>(Unaudited, U.S. Dollars, in thousands)</b>	<b>Global Spine</b>	<b>Global Extremities</b>	<b>Corporate</b>	<b>Total Orthofix</b>
<b>Operating income (loss)</b>	\$ 47,351	\$ 5,082	\$ (34,741 )	\$ 17,692
Other income (expense), net	(760 )	(1,787 )	(3,238 )	(5,785 )
Depreciation and amortization	6,099	3,878	2,882	12,859
Amortization of acquired intangibles	802	—	—	802
<b>EBITDA</b>	<b>\$ 53,492</b>	<b>\$ 7,173</b>	<b>\$ (35,097 )</b>	<b>\$ 25,568</b>
Share-based compensation	4,627	1,753	8,012	14,392
Foreign exchange impact	705	1,762	330	2,797
Strategic investments	1,615	—	10,055	11,670
Acquisition-related fair value adjustments	3,594	—	—	3,594
Loss on investment securities	—	—	3,050	3,050
Legal judgments/settlements	420	333	140	893
Succession charges	1,233	—	—	1,233
<b>Adjusted EBITDA</b>	<b>\$ 65,686</b>	<b>\$ 11,021</b>	<b>\$ (13,510 )</b>	<b>\$ 63,197</b>

**Adjusted Net Income**

<b>(Unaudited, U.S. Dollars, in thousands)</b>	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Net income (loss)	\$ (40,498 )	\$ (1,211 )	\$ (40,148 )	\$ 4,940
Foreign exchange impact	1,597	618	2,187	2,797
Strategic investments	2,120	3,804	9,014	11,672
Acquisition-related fair value adjustments	22,270	2,121	28,849	3,594
Amortization of acquired intangibles	1,338	429	3,733	802
Interest and loss on investment securities	6,017	4,449	5,328	3,050

Legal judgments/settlements	1,316	372	564	893
Succession charges	2,440	1,233	6,440	1,233
European Union Medical Device Regulation	599	—	599	—
Long-term income tax rate adjustment	10,725	(3,510 )	2,002	(5,313 )
<b>Adjusted net income</b>	<b>\$ 7,924</b>	<b>\$ 8,305</b>	<b>\$ 18,568</b>	<b>\$ 23,668</b>

#### Adjusted EPS

(Unaudited, per diluted share)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
EPS	\$ (2.14 )	\$ (0.07 )	\$ (2.13 )	\$ 0.26
Foreign exchange impact	0.08	0.03	0.11	0.15
Strategic investments	0.11	0.20	0.47	0.62
Acquisition-related fair value adjustments	1.19	0.11	1.55	0.19
Amortization of acquired intangibles	0.07	0.03	0.19	0.04
Interest and loss on investment securities	0.31	0.23	0.28	0.16
Legal judgments/settlements	0.07	0.02	0.03	0.05
Succession charges	0.13	0.06	0.33	0.06
European Union Medical Device Regulation	0.03	—	0.03	—
Long-term income tax rate adjustment	0.56	(0.17 )	0.10	(0.28 )
<b>Adjusted EPS</b>	<b>\$ 0.41</b>	<b>\$ 0.44</b>	<b>\$ 0.96</b>	<b>\$ 1.25</b>

Weighted average number of diluted common shares (treasury stock method)	19,306,006	18,975,386	19,290,124	18,985,060
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#### Free Cash Flow

(Unaudited, U.S. Dollars, in thousands)	Nine Months Ended September 30,	
	2019	2018
Net cash from operating activities	\$ 20,090	\$ 28,829



Capital expenditures (14,881) (10,724)

**Free cash flow \$ 5,209 \$ 18,105**

**2019 Outlook**

<b>(Unaudited, U.S. Dollars, in millions)</b>	<b>Previous 2019 Outlook</b>		<b>Current 2019 Outlook</b>	
	<b>Low</b>	<b>High</b>	<b>Low</b>	<b>High</b>
Net income	\$ 12.7	\$ 13.6	\$ (24.3 )	\$ (22.8 )
Interest expense, net	(1.2 )	(1.2 )	(0.4 )	(0.4 )
Income tax expense	6.8	7.3	3.9	3.7
Depreciation and amortization	24.5	24.6	24.5	24.5
EBITDA	\$ 42.8	\$ 44.3	\$ 3.7	\$ 5.0
Share-based compensation	19.3	20.4	16.6	17.0
Foreign exchange impact	0.6	0.6	2.2	2.2
Strategic investments	8.7	8.9	10.0	10.3
Acquisition-related fair value adjustments	7.7	7.7	29.6	29.6
Interest and loss on investment securities	—	—	6.5	6.5
Legal judgments/settlements	(0.5 )	(0.5 )	0.7	0.7
Succession charges	7.4	7.6	8.0	8.0
European Union Medical Device Regulation	—	—	0.7	0.7
<b>Adjusted EBITDA</b>	<b>\$ 86.0</b>	<b>\$ 89.0</b>	<b>\$ 78.0</b>	<b>\$ 80.0</b>

<b>(Unaudited, per diluted share)</b>	<b>Previous 2019 Outlook</b>		<b>Current 2019 Outlook</b>	
	<b>Low</b>	<b>High</b>	<b>Low</b>	<b>High</b>
EPS	\$ 0.66	\$ 0.70	\$ (1.25 )	\$ (1.18 )
Foreign exchange impact	0.03	0.03	0.11	0.11
Strategic investments	0.45	0.46	0.52	0.53
Acquisition-related fair value adjustments	0.40	0.40	1.53	1.53
Amortization of intangible assets	0.25	0.26	0.26	0.26
Interest and loss on investment securities	(0.09 )	(0.09 )	0.27	0.27

Legal judgments/settlements	(0.02 )	(0.02 )	0.04	0.04
Succession charges	0.38	0.39	0.41	0.41
European Union Medical Device Regulation	—	—	0.04	0.04
Long-term income tax rate adjustment	(0.31 )	(0.31 )	(0.38 )	(0.41 )
<b>Adjusted EPS</b>	<b>\$ 1.75</b>	<b>\$ 1.82</b>	<b>\$ 1.55</b>	<b>\$ 1.60</b>
Weighted average number of diluted common shares (treasury stock method)	19,375,000	19,375,000	19,375,000	19,375,000

### 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 expense, net; income tax (expense)/benefit; and depreciation and amortization to net income/(loss). 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 awards, performance-based restricted stock awards, market-based restricted stock awards and our stock purchase plan; see the share-based compensation footnote in our Form 10-Q for the quarter ended September 30, 2019 for a detail of these costs by consolidated statement of income line item; however, certain share-based compensation costs have been included within succession charges for 2019
- *Foreign exchange impact* – gains and losses related to foreign currency transactions, which are recorded as other expense, net; guidance presented does not include the impact of any future foreign exchange fluctuations
- *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 Curaçao to the State of Delaware during 2018, which are primarily recorded as general and administrative expenses.

Amounts previously reported as “Domestication to Delaware” have been reclassified to this line item to conform to current period presentation, resulting in an increase in strategic investments of \$1.0 million and \$3.7 million for the three and nine months ended September 30, 2018

- *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 \$0.04 and \$0.05 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 three and nine months ended September 30, 2019, respectively, 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, in process research and development, trade names, and other intangible assets, which are recorded as operating expenses
- *Interest and loss on investment securities* – net losses recognized within other expense, net, or amortization of historical unrealized gains previously recorded within accumulated other comprehensive income to interest income relating to our investments in eNeura Inc. and Bone Biologics, Inc.

- *Legal judgments/settlements* – adverse or favorable legal judgments or negotiated legal settlements, including legal and other professional fees associated with the SEC Investigation, Securities Class Action Complaints and Brazil subsidiary compliance review, which are recorded as general and administrative expenses
- *Succession charges* – costs related to the transition of the Company's named executive officers, including any cessation and onboarding amounts, accelerated share-based compensation expense, consulting services and other related expenses
- *European Union Medical Device Regulation* – incremental costs incurred to establish initial compliance with the regulations set forth by the European Union Medical Device Regulation related to our currently-approved medical devices; the new regulations provide a transition period until May 2020 for currently-approved medical devices to meet the additional requirements and for certain devices this transition period can be extended until May 2024; these incremental costs primarily include third-party consulting costs necessary to supplement our internal resources and are recorded as research and development expenses
- *Long-term income tax rate adjustment* – reflects management's expectation of a long-term normalized effective tax rate of 35% for the first and second quarters of 2018, 29% for the third and fourth quarters of 2018, and 27% for our 2019 results and outlook, which is based on current tax law and current expected 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

### **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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