UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 24, 2020

ORTHOFIX MEDICAL INC.

(Exact name of Registrant as specified in its charter)

Delaware	**0-19961**	**98-1340767**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3451 Plano Parkway	
Lewisville, Texas	**75056**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (214) 937-2000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.10 par value per share	OFIX	Nasdaq Global Select Market

Item 2.02. Results of Operations and Financial Condition.

On February 24, 2020, Orthofix Medical Inc. (the "Company") issued a press release announcing, among other things, its financial results for the fiscal quarter and year ended December 31, 2019. A copy of the press release is furnished herewith as Exhibit 99.1 and attached hereto.

The information furnished in this Item 2.02, including the exhibit furnished herewith as Exhibit 99.1, will not be treated as "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. This information will not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or into another filing under the Exchange Act, unless that filing expressly incorporates by reference this Item 2.02 of this report.

Item 7.01 Regulation FD Disclosure.

The press release furnished in Exhibit 99.1 also provides an update on the Company's business outlook, that is intended to be within the safe harbor provided by the Private Securities Litigation Reform Act of 1995 (the "Act") as comprising forward looking statements within the meaning of the Act.

In addition, on February 24, 2020 the Company issued a press release announcing support for continued U.S. Food and Drug Administration Class III designation for bone growth stimulators to ensure patient safety and therapy efficacy. A copy of the press release is furnished herewith as Exhibit 99.2 and attached hereto.

The information furnished in this Item 7.01, including the exhibits furnished herewith as Exhibit 99.1 and Exhibit 99.2, will not be treated as "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section. This information will not be deemed incorporated by reference into any filing under the Securities Act, or into another filing under the Exchange Act, unless that filing expressly incorporates by reference this Item 7.01 of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release, dated February 24, 2020.
99.2	Press release, dated February 24, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Orthofix Medical Inc.

By: /s/ Kimberley A. Elting
Kimberley A. Elting
Chief Legal and Administrative Officer

Date: February 25, 2020

Orthofix Reports Fourth Quarter and Fiscal Year 2019 Financial Results

Fourth Quarter Highlights

- Net sales of $121.5 million, an increase of 0.3% compared to prior year period and 0.9% on a constant currency basis
- Kevin Kenny, an experienced spine executive, joins as Global Spine President
- FDA approval of next generation Bone Growth Therapy patient monitoring app STIM onTrack 2.1

Fiscal Year 2019 Highlights

- Net sales of $460.0 million, an increase of 1.5% compared to prior year and 2.6% on a constant currency basis
- M6-C artificial disc achieves $4.1 million in sales in the US
- Successful transition to Jon Serbousek as CEO

LEWISVILLE, Texas — February 24, 2020 — Orthofix Medical Inc. (NASDAQ:OFIX) today reported its financial results for the fourth quarter and fiscal year ended December 31, 2019. For the fourth quarter of 2019, net sales were $121.5 million, earnings per share ("EPS") was $0.60 and adjusted EPS was $0.51. For fiscal year 2019, net sales were $460.0 million, EPS was ($1.51) and adjusted EPS was $1.47.

"I joined Orthofix because I saw a significant opportunity. The last few months spent with this talented team and our external stakeholders has me even more excited about the future of this Company," said Jon Serbousek, President and Chief Executive Officer. "We have well defined market and technology leadership positions in bone growth stimulation, cellular based allografts, extremity deformity correction, and artificial disc replacement. This combined with the solid infrastructure we have in place gives us the platform to scale in all of our businesses. We are already executing on our recently developed Strategic Plan, which we believe will accelerate our growth and maximize shareholder value."

Serbousek further commented, "During the fourth quarter, revenue from the M6 cervical disc in the U.S. outpaced our expectations, which highlights the significant opportunity we have with this technology. While some of our other product categories experienced some headwinds due to continued distraction, we believe we are putting the pieces in place to reposition Orthofix for accelerating topline growth."

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)	**2019**	**2018**	**Change**	**Constant Currency Change**
Bone Growth Therapies	$ 50,953	$ 52,819	(3.5%)	(3.5%)
Spinal Implants	25,468	24,969	2.0%	2.3%
Biologics	16,712	16,045	4.2%	4.2%
Global Spine	93,133	93,833	(0.7%)	(0.7%)
Global Extremities	28,361	27,245	4.1%	6.4%
Net sales	**$ 121,494**	**$ 121,078**	**0.3%**	**0.9%**

Gross profit decreased by $0.1 million to $95.3 million and gross margin decreased slightly to 78.4%, compared to 78.8% in the prior year period.

Net income was $11.7 million, or $0.60 per share, compared to net income of $8.9 million, or $0.46 per share in the prior year period. Adjusted net income was $9.9 million, or $0.51 per share, compared to adjusted net income of $10.7 million, or $0.56 per share in the prior year period.

EBITDA was $11.3 million, compared to $16.8 million in the prior year period. Adjusted EBITDA was $22.5 million, or 18.5% of net sales, compared to $24.4 million, or 20.2% of net sales, in the prior year period.

Fiscal Year 2019

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

	Year Ended December 31,			
(U.S. Dollars, in thousands)	**2019**	**2018**	**Change**	**Constant Currency Change**
Bone Growth Therapies	$ 197,181	$ 195,252	1.0%	1.0%
Spinal Implants	94,544	91,658	3.1%	3.8%
Biologics	65,496	59,684	9.7%	9.7%
Global Spine	357,221	346,594	3.1%	3.2%
Global Extremities	102,734	106,448	(3.5%)	0.3%
Net sales	**$ 459,955**	**$ 453,042**	**1.5%**	**2.6%**

Gross profit increased $2.9 million to $359.3 million, while gross margin decreased to 78.1%, compared to 78.7% in prior year.

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 indicate a greater likelihood of achieving the potential revenue-based milestone payments associated with the Spinal Kinetics acquisition as compared to our original projections in 2018. As such, we recognized expenses during the year of $29.1 million associated with the remeasurement of these potential milestone payment liabilities.

Net loss was ($28.5) million, or ($1.51) per share, compared to net income of $13.8 million, or $0.72 per share, in the prior year. This decrease was primarily driven by the remeasurement of the potential Spinal Kinetics milestone payment liabilities discussed above. Adjusted net income was $28.4 million, or $1.47 per share, compared to adjusted net income of $34.4 million, or $1.81 per share, in the prior year.

EBITDA was ($2.2) million, compared to $42.4 million in the prior year, largely due to the remeasurement of the potential Spinal Kinetics milestone payment liabilities, losses on investment securities, and succession and transition charges. Adjusted EBITDA was $75.7 million, or 16.5% of net sales for the year, compared to $87.6 million, or 19.3% of net sales, in the prior year.

Liquidity

As of December 31, 2019, cash, cash equivalents, and restricted cash totaled $70.4 million compared to $72.2 million as of December 31, 2018. Cash flow from operations decreased $17.9 million to $32.0 million when compared to the prior year, while free cash flow decreased $23.2 million to $11.5 million.

As of December 31, 2019, the Company had no outstanding indebtedness and borrowing capacity of $300 million under its credit facility.

FitBone

As recently announced, we entered into an asset purchase agreement with Wittenstein SE, a privately-held German-based company, to acquire assets associated with the FITBONE® intramedullary lengthening system for limb lengthening of the femur and tibia bones. The addition of the FITBONE assets will further round out the Company’s limb reconstruction offerings, and will align with our strategy of investing in innovative products to drive growth within our core businesses. We expect the transaction to close at the end of March.

2020 Outlook

For the year ending December 31, 2020, the Company expects the following results, including the impact of any expected changes in foreign currency exchange rates.

	2020 Outlook	
(Unaudited, U.S. Dollars, in millions, except per share data)	**Low**	**High**
Full Year 2020		
Net sales	$ 467.0 [1]	$ 477.0 [1]
Adjusted EBITDA	$ 65.0 [2]	$ 68.0 [2]
Adjusted EPS	$ 1.00 [3]	$ 1.10 [3]
First Quarter 2020		
Net sales	$ 106.0 [4]	$ 109.0 [4]
Adjusted EBITDA	$ 10.5 [5]	$ 11.5 [5]
Adjusted EPS	$ 0.09 [6]	$ 0.12 [6]

1 Represents a year-over-year increase of 1.5% to 3.7% on a reported basis and 2.3% to 4.5% on a constant currency basis
2 Represents a year-over-year decrease of 14.2% to 10.2%
3 Represents a year-over-year decrease of 32.0% to 25.2%
4 Represents a year-over-year decrease of 2.9% to 0.1% on a reported basis and a decrease of 1.0% to an increase of 1.7% on a constant currency basis
5 Represents a year-over-year decrease of 33.0% to 26.6%
6 Represents a year-over-year decrease of 66.7% to 55.6%

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 4:30 PM Eastern time to discuss the Company's financial results for the fourth quarter and fiscal year 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 8228975. 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 8228975. A webcast of the conference call may be accessed by going to the Company's website at 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 more than 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 ("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, 2019, to reflect new information, the occurrence of future events or circumstances or otherwise.

Company Contact

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ORTHOFIX MEDICAL INC.
Condensed Consolidated Statements of Operations

(U.S. Dollars, in thousands, except share and per share data)	Three Months Ended December 31, 2019	Three Months Ended December 31, 2018	Year Ended December 31, 2019	Year Ended December 31, 2018
	(unaudited)			
Net sales	$ 121,494	$ 121,078	$ 459,955	$ 453,042
Cost of sales	26,191	25,626	100,607	96,628
Gross profit	95,303	95,452	359,348	356,414
Sales and marketing	58,313	53,832	223,676	205,527
General and administrative	22,110	19,593	85,607	83,251
Research and development	8,446	8,792	34,637	33,218
Acquisition-related amortization and remeasurement	2,339	833	34,212	4,324
Operating income (loss)	4,095	12,402	(18,784)	30,094
Interest expense, net	(508)	(213)	(122)	(828)
Other income (expense), net	643	(596)	(8,143)	(6,381)
Income (loss) before income taxes	4,230	11,593	(27,049)	22,885
Income tax benefit (expense)	7,456	(2,722)	(1,413)	(9,074)
Net income (loss)	**$ 11,686**	**$ 8,871**	**$ (28,462)**	**$ 13,811**
Net income (loss) per common share:				
Basic	$ 0.61	$ 0.47	$ (1.51)	$ 0.73
Diluted	0.60	0.46	(1.51)	0.72
Weighted average number of common shares:				
Basic	19,068,067	18,592,385	18,903,289	18,494,002
Diluted	19,315,836	19,052,853	18,903,289	18,911,610

Condensed Consolidated Balance Sheets

(U.S. Dollars, in thousands, except share data)	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 69,719	$ 69,623
Restricted cash	684	2,566
Trade accounts receivable, net of allowances of $3,987 and $7,463, respectively	86,805	77,747
Inventories	82,397	76,847
Prepaid expenses and other current assets	20,948	17,856
Total current assets	260,553	244,639
Property, plant and equipment, net	62,727	42,835
Intangible assets, net	54,139	51,897
Goodwill	71,177	72,401
Deferred income taxes	35,117	33,228
Other long-term assets	11,907	21,641
Total assets	**$ 495,620**	**$ 466,641**
Liabilities and shareholders' equity		
Current liabilities		
Trade accounts payable	$ 19,886	$ 17,989
Current portion of finance lease liability	323	—
Other current liabilities	64,674	67,919
Total current liabilities	84,883	85,908
Long-term portion of finance lease liability	20,648	—
Other long-term liabilities	62,458	45,336
Total liabilities	167,989	131,244
Contingencies		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 19,022,619 and 18,579,688 issued and outstanding as of December 31, 2019 and 2018, respectively	1,902	1,858
Additional paid-in capital	271,019	243,165
Retained earnings	57,749	87,078
Accumulated other comprehensive income (loss)	(3,039)	3,296
Total shareholders' equity	327,631	335,397
Total liabilities and shareholders' equity	**$ 495,620**	**$ 466,641**

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, 2019			
(Unaudited, U.S. Dollars, in thousands)	**Global Spine**	**Global Extremities**	**Corporate**	**Total 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			
(Unaudited, U.S. Dollars, in thousands)	**Global Spine**	**Global Extremities**	**Corporate**	**Total Orthofix**
Operating income (loss)	$ 25,722	$ 2,872	$ (47,378)	$ (18,784)
Other 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**

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended December 31, 2018			
	Global Spine	Global Extremities	Corporate	Total Orthofix
Operating income (loss)	$ 20,605	$ 924	$ (9,127)	$ 12,402
Other expense, net	(164)	(107)	(325)	(596)
Depreciation and amortization	2,159	1,463	923	4,545
Amortization of acquired intangibles	453	—	—	453
EBITDA	$ 23,053	$ 2,280	$ (8,529)	$ 16,804
Share-based compensation	1,632	498	2,408	4,538
Foreign exchange impact	130	70	332	532
Strategic investments	348	—	793	1,141
Acquisition-related fair value adjustments	914	—	—	914
Loss on investment securities	—	—	—	—
Legal judgments/settlements	266	172	(171)	267
Succession and transition charges	214	—	—	214
Adjusted EBITDA	**$ 26,557**	**$ 3,020**	**$ (5,167)**	**$ 24,410**

(Unaudited, U.S. Dollars, in thousands)	Year Ended December 31, 2018			
	Global Spine	Global Extremities	Corporate	Total Orthofix
Operating income (loss)	$ 67,956	$ 6,006	$ (43,868)	$ 30,094
Other expense, net	(924)	(1,894)	(3,563)	(6,381)
Depreciation and amortization	8,258	5,341	3,805	17,404
Amortization of acquired intangibles	1,255	—	—	1,255
EBITDA	$ 76,545	$ 9,453	$ (43,626)	$ 42,372
Share-based compensation	6,259	2,251	10,420	18,930
Foreign exchange impact	835	1,832	662	3,329
Strategic investments	1,963	—	10,848	12,811
Acquisition-related fair value adjustments	4,508	—	—	4,508
Loss on investment securities	—	—	3,050	3,050
Legal judgments/settlements	686	505	(31)	1,160
Succession and transition charges	1,447	—	—	1,447
Adjusted EBITDA	**$ 92,243**	**$ 14,041**	**$ (18,677)**	**$ 87,607**

Adjusted Net Income

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Net income (loss)	$ 11,686	$ 8,871	$ (28,462)	$ 13,811
Foreign exchange impact	(753)	532	1,434	3,329
Strategic investments	471	1,141	9,485	12,813
Acquisition-related fair value adjustments	1,000	914	29,849	4,508
Amortization of acquired intangibles	1,339	453	5,072	1,255
Interest and loss on investment securities	—	—	5,328	3,050
Legal judgments/settlements	1,989	267	2,553	1,160
Succession and transition charges	4,887	214	11,327	1,447
Medical Device Regulation	354	—	953	—
Long-term income tax rate adjustment	(11,106)	(1,662)	(9,104)	(6,975)
Adjusted net income	**$ 9,867**	**$ 10,730**	**$ 28,435**	**$ 34,398**

Adjusted EPS

(Unaudited, per diluted share)	Three Months Ended December 31, 2019	Three Months Ended December 31, 2018	Year Ended December 31, 2019	Year Ended December 31, 2018
EPS	$ 0.60	$ 0.46	$ (1.51)	$ 0.72
Foreign exchange impact	(0.04)	0.03	0.07	0.17
Strategic investments	0.02	0.06	0.49	0.67
Acquisition-related fair value adjustments	0.05	0.05	1.58	0.24
Amortization of acquired intangibles	0.07	0.02	0.26	0.07
Interest and loss on investment securities	—	—	0.28	0.16
Legal judgments/settlements	0.10	0.01	0.13	0.06
Succession and transition charges	0.25	0.01	0.59	0.08
Medical Device Regulation	0.02	—	0.05	—
Long-term income tax rate adjustment	(0.56)	(0.08)	(0.47)	(0.36)
Adjusted EPS	**$ 0.51**	**$ 0.56**	**$ 1.47**	**$ 1.81**
Weighted average number of diluted common shares (treasury stock method)	19,341,552	19,195,653	19,303,457	19,037,978

Free Cash Flow

(Unaudited, U.S. Dollars, in thousands)	Year Ended December 31, 2019	Year Ended December 31, 2018
Net cash from operating activities	$ 32,033	$ 49,918
Capital expenditures	(20,524)	(15,256)
Free cash flow	**$ 11,509**	**$ 34,662**

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-K for the year ended December 31, 2019 for a detail of these costs by consolidated statement of operations 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 income (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 $0.5 million and $4.2 million for the three months and year ended December 31, 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 $0.03 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, 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 and transition charges* – costs related to the transition of the Company's named executive officers and certain targeted restructuring costs, including any cessation and onboarding amounts, accelerated share-based compensation expense, consulting services, and other related expenses, which are recorded as general and administrative expenses
- *Medical Device Regulation* – incremental costs incurred 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 regulation provides 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; the incremental costs to comply with these regulations 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 and 2020 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.

Source

Orthofix Medical Inc.

Exhibit 99.2

Orthofix Announces Support for Continued FDA Class III Designation for Bone Growth Stimulators to Ensure Patient Safety and Therapy Efficacy

LEWISVILLE, TX. – February 24, 2020 – Orthofix Medical Inc. (NASDAQ:OFIX), a global medical device company focused on musculoskeletal healing products, announces support for the continued U.S. Food and Drug Administration (FDA) Class III designation for Bone Growth Stimulators to ensure patient safety and therapy efficacy. The FDA has announced that they will hold an Advisory Committee panel meeting on April 23 to consider whether Bone Growth Stimulator (BGS) devices should be reclassified from Class III to Class II medical devices. Class III devices are subject to the most rigorous pathway to approval for medical devices. The FDA may change classification of a device only if the proposed new class has sufficient regulatory controls to provide reasonable assurances of safety and effectiveness.

“Bone Growth Stimulation devices should remain regulated in a way that appropriately reflects the known benefits and risks for specific indications for use by requiring that manufacturers submit clinical data, through the FDA’s pre-market approval process, to demonstrate safety and effectiveness,” said Orthofix President and Chief Executive Officer Jon Serbousek. “This gives physicians more information on the safe and effective use of these devices and ultimately better protects patients.”

The Advisory Committee panel meeting follows the 2015 listing of bone growth stimulator products along with now 31 other product categories as candidates for possible down classification. The purpose of the listing and review by the FDA of these 32 product categories was to further one of the FDA’s general strategic priorities of reducing regulatory burdens. In 2006, FDA convened an advisory panel and ultimately determined, for safety and efficacy reasons, to maintain the Class III status for BGS devices.

“Bone Growth Stimulation devices encompass a range of intended uses, distinct technologies, waveform parameters, functionalities, dosimetries, and designs,” continued Serbousek. “Given the nature of and dissimilarities among these devices, a single set of special controls could not reasonably assure the safety and effectiveness of each distinct type of BGS device. Simply stated, these are not 510K devices even with special controls.”

Together with the other manufacturers of bone growth stimulators, Orthofix will participate in the April hearing, as it did in 2006, and submit testimony supporting the importance of maintaining BGS devices as Class III devices. Evidence to be presented will include:

- Bone growth stimulation devices cannot be defined as “generic,” which is a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function or any other feature related to safety and effectiveness
- Special controls cannot be established to assure the safety and effectiveness of BGS devices due to dissimilarities among the PMA-approved devices from various manufacturers
- Insufficient valid scientific evidence exists to determine that special controls would provide reasonable assurance of their safety and effectiveness
- Risks to health cannot be mitigated through general and special controls

Orthofix has the market-leading Bone Growth Stimulation platform with the only cervical spinal indication granted by the FDA, and the only mobile device app accessory designed to help patients adhere to their prescriptions and improve their clinical outcomes, STIM onTrack™ 2.1. Orthofix is also investing in investigational device exemption (IDE) studies to expand indications for use in areas such as rotator cuff tears. Together with the other manufacturers of bone growth stimulators, Orthofix will participate in the hearing and submit testimony supporting the importance of maintaining these devices as Class III devices.

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 more than 70 countries via the Company's sales representatives and distributors. For more information, please visit www.orthofix.com.

Forward Looking Statements
This communication contains certain forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements, which may include, but are not limited to, statements concerning the estimates, projections, financial condition, results of operations and businesses of Orthofix and its subsidiaries, are based on Orthofix management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements.

The forward-looking statements in this release do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to: practices of health insurance companies and other third-party payors with respect to reimbursement for our PEMF devices and other risks described in the "Risk Factors" section of our 2019 Annual Report on Form 10-K, as well as in other reports that we file in the future. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update or revise the information contained in this press release

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