

ORTHOFIX INTERNATIONAL N V

FORM 8-K (Current report filing)

Filed 05/04/17 for the Period Ending 05/04/17

Telephone	214-937-2000
CIK	0000884624
Symbol	OFIX
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

**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): May 4, 2017

Orthofix International N.V.

(Exact name of Registrant as specified in its charter)

Curaçao
(State or other jurisdiction
of incorporation)

0-19961
(Commission
File Number)

98-1340767
(IRS Employer
Identification No.)

7 Abraham de Veerstraat Curaçao
(Address of principal executive offices)

N/A
(Zip Code)

Registrant's telephone number, including area code: 011-59-99-465-8525

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.

Item 2.02. Results of Operations and Financial Condition.

On May 4, 2017, Orthofix International N.V. (the “Company”) issued a press release announcing, among other things, its financial results for the fiscal quarter ended March 31, 2017. 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 incorporated by reference, 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 refers to specific information in 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.

The information furnished in this Item 7.01, including the exhibit incorporated by reference, 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 refers to specific information in this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated May 4, 2017.

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 International N.V.

By: /s/ Kimberley Elting
Kimberley Elting
Chief Legal Officer

Date: May 4, 2017

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 4, 2017.



Orthofix International Reports First Quarter 2017 Financial Results

First Quarter Highlights

- Net sales of \$102.7 million, an increase of 4.1% compared to prior year or 4.6% on a constant currency basis
- BioStim sales of \$44.5 million, an increase of 8.5% compared to prior year
- Biologics sales of \$15.0 million, an increase of 6.3% compared to prior year
- Spine Fixation sales of \$19.3 million, an increase of 2.3% compared to prior year

LEWISVILLE, Texas — May 4, 2017 — Orthofix International N.V. (NASDAQ:OFIX) today reported its financial results for the first quarter ended March 31, 2017. Net sales were \$102.7 million, loss per share from continuing operations was (\$0.13) and adjusted earnings per share from continuing operations was \$0.27.

“We are very pleased with the top-line results for the first quarter 2017 and the momentum we achieved in each of our businesses,” said Brad Mason, President and Chief Executive Officer. “The solid execution of our commercial strategies is delivering results as demonstrated by another strong quarter in our BioStim business and an earlier than expected return to growth in both Biologics and Spine Fixation. Although each strategic business unit has its own commercial strategy, our overriding corporate focus is on expanding distribution in underserved markets, improving engagement of our legacy distributors and providing our salesforce with a robust stream of new products. Our bottom-line results reflect the investments we are making in these key strategies, which are proving effective in driving our top line growth.”

Financial Results Overview

The following table provides net sales by strategic business unit (“SBU”):

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended March 31,				
	2017	2016	Change	Constant Currency Change	
BioStim	\$ 44,539	\$ 41,044	8.5%	8.5%	
Biologics	14,987	14,094	6.3%	6.3%	
Extremity Fixation	23,945	24,709	(3.1%)	(1.0%)	
Spine Fixation	19,267	18,832	2.3%	2.3%	
Net sales	\$ 102,738	\$ 98,679	4.1%	4.6%	

Gross profit increased \$3.6 million to \$80.2 million. Gross margin increased slightly to 78.0% compared to 77.6% in the prior year period, which was in line with our expectations. Net margin (gross profit less sales and marketing expenses) was \$31.6 million compared to \$31.7 million in the prior year period. The decrease in net margin was primarily due to higher sales and marketing expenses, driven by a higher mix of sales from new distributors in our Biologics and Spine Fixation SBUs, who typically receive higher commission rates in their first year.

Net loss from continuing operations was (\$2.3) million, or (\$0.13) per share, compared to net income of \$4.6 million, or \$0.24 per share in the prior year period. The net loss for the quarter was impacted by strategic investments in the quarter of \$7.1 million, including a pre-tax impairment of \$5.6 million on our eNeura investment. Adjusted net income from continuing operations was \$4.9 million, or \$0.27 per share, compared to adjusted net income of \$5.2 million, or \$0.28 per share in the prior year period.

EBITDA was \$6.6 million, compared to \$13.8 million in the prior year period. Adjusted EBITDA was \$15.7 million or 15.3% of net sales for the first quarter, compared to \$15.5 million or 15.7% of net sales in the prior year period.

Liquidity

As of March 31, 2017, cash and cash equivalents were \$41.7 million compared to \$39.6 million as of December 31, 2016. As of March 31, 2017, we had no outstanding indebtedness and borrowing capacity of \$125 million. Cash flow from operations decreased \$1.2 million to \$3.5 million, while free cash flow increased \$1.3 million to (\$0.4) million.

2017 Outlook

For the year ending December 31, 2017, the Company expects the following results, assuming exchange rates are the same as those currently prevailing.

(Unaudited, U.S. Dollars, in millions, except per share data)	Previous 2017 Outlook		Current 2017 Outlook	
	Low	High	Low	High
Net sales	\$ 407.0	\$ 411.0	\$ 411.0 ¹	\$ 415.0 ¹
Net income from continuing operations	\$ 24.4	\$ 29.3	\$ 20.6 ²	\$ 23.7 ²
Adjusted EBITDA	\$ 76.0	\$ 79.0	\$ 76.0 ³	\$ 79.0 ³
EPS from continuing operations	\$ 1.33	\$ 1.59	\$ 1.12 ⁴	\$ 1.29 ⁴
Adjusted EPS from continuing operations	\$ 1.48	\$ 1.58	\$ 1.48 ⁵	\$ 1.58 ⁵

¹ Represents a year-over-year increase of 0.3% to 1.3% on a reported basis

² Represents a year-over-year increase of 489.1% to 577.7%

³ Represents a year-over-year decrease of 0.4% to 4.2%

⁴ Represents a year-over-year increase of 489.5% to 578.9%

⁵ Represents a year-over-year increase of 1.4% to 8.2%

Conference Call

Orthofix will host a conference call today at 4:30 PM Eastern time to discuss the Company's financial results for the first quarter of 2017. Interested parties may access the conference call by dialing (888) 364-3109 in the U.S. and (719) 457-2631 outside the U.S., and referencing the conference ID 9028875. A replay of the call will be available for two weeks by dialing (888) 203-1112 in the U.S. and (719) 457-0820 outside the U.S., and entering the conference ID 9028875. 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 International N.V. is a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, Texas, the Company has four strategic business units: BioStim, Biologics, Extremity Fixation and Spine Fixation. Orthofix products are widely distributed via the Company's sales representatives and distributors. In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as Brown University, Sinai Hospital of Baltimore, Cleveland Clinic, Texas Scottish Rite Hospital for Children, and the Musculoskeletal Transplant Foundation. 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, 2016, to reflect new information, the occurrence of future events or circumstances or otherwise.

Company Contact

Orthofix International N.V.

Mark Quick

P: 214-937-2924

E: markquick@orthofix.com

ORTHOFIX INTERNATIONAL N.V.
Consolidated Statements of Operations

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended	
	2017	March 31, 2016
Net sales	\$ 102,738	\$ 98,679
Cost of sales	22,581	22,137
Gross profit	80,157	76,542
Sales and marketing	48,532	44,822
General and administrative	18,282	17,005
Research and development	7,424	7,640
Operating income	5,919	7,075
Interest income (expense), net	45	(38)
Other income (expense), net	(4,348)	1,833
Income before income taxes	1,616	8,870
Income tax expense	(3,924)	(4,294)
Net income (loss) from continuing operations	(2,308)	4,576
Discontinued operations		
Loss from discontinued operations	(527)	(990)
Income tax benefit	181	254
Net loss from discontinued operations	(346)	(736)
Net income (loss)	\$ (2,654)	\$ 3,840
Net income (loss) per common share—basic		
Net income (loss) from continuing operations	\$ (0.13)	\$ 0.25
Net loss from discontinued operations	(0.02)	(0.04)
Net income (loss) per common share—basic	\$ (0.15)	\$ 0.21
Net income (loss) per common share—diluted		
Net income (loss) from continuing operations	\$ (0.13)	\$ 0.24
Net loss from discontinued operations	(0.02)	(0.04)
Net income (loss) per common share—diluted	\$ (0.15)	\$ 0.20
Weighted average number of common shares:		
Basic	17,979,675	18,477,881
Diluted	17,979,675	18,758,751

ORTHOFIX INTERNATIONAL N.V.
Consolidated Balance Sheets

(U.S. Dollars, in thousands except share data)	March 31, 2017 (unaudited)	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	\$ 41,652	\$ 39,572
Restricted cash	—	14,369
Accounts receivable, net of allowances of \$8,394 and \$8,396, respectively	59,443	57,848
Inventories	66,271	63,346
Prepaid expenses and other current assets	19,478	19,238
Total current assets	186,844	194,373
Property, plant and equipment, net	47,962	48,916
Patents and other intangible assets, net	8,530	7,461
Goodwill	53,565	53,565
Deferred income taxes	41,431	47,325
Other long-term assets	16,413	20,463
Total assets	\$ 354,745	\$ 372,103
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	\$ 16,555	\$ 14,353
Other current liabilities	46,316	69,088
Total current liabilities	62,871	83,441
Other long-term liabilities	24,740	25,185
Total liabilities	87,611	108,626
Contingencies		
Shareholders' equity		
Common shares \$0.10 par value; 50,000,000 shares authorized; 18,042,834 and 17,828,155 issued and outstanding as of March 31, 2017 and December 31, 2016, respectively	1,804	1,783
Additional paid-in capital	208,686	204,095
Retained earnings	61,525	64,179
Accumulated other comprehensive loss	(4,881)	(6,580)
Total shareholders' equity	267,134	263,477
Total liabilities and shareholders' equity	\$ 354,745	\$ 372,103

ORTHOFIX INTERNATIONAL N.V.
Non-GAAP Financial Measures

The following tables present reconciliations of net income (loss) from continuing operations, earnings per share from continuing operations, gross profit, 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 from continuing operations," "Adjusted earnings per share from continuing operations," "Net margin" 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

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended March 31,	
	2017	2016
Net income (loss) from continuing operations	\$ (2,308)	\$ 4,576
Interest expense (income), net	(45)	38
Income tax expense	3,924	4,294
Depreciation and amortization	5,075	4,873
EBITDA	\$ 6,646	\$ 13,781
Share-based compensation	2,816	2,099
Foreign exchange impact	(1,013)	(1,815)
Strategic investments	7,100	198
SEC / FCPA matters and related costs	141	245
Infrastructure investments	—	962
Legal judgments/settlements	227	—
International restructuring	(239)	—
Adjusted EBITDA	\$ 15,678	\$ 15,470
As a % of net sales	15.3%	15.7%

Adjusted Net Income from Continuing Operations

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended March 31,	
	2017	2016
Net income (loss) from continuing operations	\$ (2,308)	\$ 4,576
Foreign exchange impact	(1,013)	(1,815)
Strategic investments	7,100	198
SEC / FCPA matters and related costs	141	245
Infrastructure investments	—	962
Legal judgments/settlements	227	—
International restructuring	(239)	—
Long-term income tax rate adjustment	948	1,079
Adjusted net income from continuing operations	\$ 4,856	\$ 5,245

Adjusted Earnings per Share from Continuing Operations

(Unaudited, per diluted share)	Three Months Ended March 31,	
	2017	2016
EPS from continuing operations	\$ (0.13)	\$ 0.24
Foreign exchange impact	(0.06)	(0.10)
Strategic investments	0.39	0.01
SEC / FCPA matters and related costs	0.01	0.01
Infrastructure investments	—	0.05
Legal judgments/settlements	0.01	—
International restructuring	(0.01)	—
Long-term income tax rate adjustment	0.06	0.07
Adjusted EPS from continuing operations	\$ 0.27	\$ 0.28
Weighted average number of diluted common shares	18,235,660	18,758,751

Net Margin

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended March 31,	
	2017	2016
Gross profit	\$ 80,157	\$ 76,542
Sales and marketing	(48,532)	(44,822)
Net margin	\$ 31,625	\$ 31,720
BioStim	\$ 17,133	\$ 16,408
Biologics	6,171	6,104
Extremity Fixation	6,412	7,175
Spine Fixation	2,007	2,335
Corporate	(98)	(302)
Net margin	\$ 31,625	\$ 31,720

Free Cash Flow

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended March 31,	
	2017	2016
Net cash from operating activities	\$ 3,470	\$ 4,646
Capital expenditures	(3,905)	(6,399)
Free cash flow	\$ (435)	\$ (1,753)

2017 Outlook

(Unaudited, U.S. Dollars, in millions)	Previous 2017 Outlook		Current 2017 Outlook	
	Low	High	Low	High
Net income from continuing operations	\$ 24.4	\$ 29.3	\$ 20.6	\$ 23.7
Interest expense, net	0.1	0.2	0.1	0.2
Income tax expense	16.2	15.7	13.6	14.3
Depreciation and amortization	20.0	20.0	20.0	20.0
EBITDA	\$ 60.7	\$ 65.2	\$ 54.3	\$ 58.2
Share-based compensation	11.8	11.8	11.8	11.8
Foreign exchange impact	—	—	(1.0)	(1.0)
Strategic investments	1.2	0.7	8.6	8.1
SEC / FCPA matters and related costs	1.3	0.8	1.3	1.0
International restructuring	1.0	0.5	0.8	0.7
Legal judgments/settlements	—	—	0.2	0.2
Adjusted EBITDA	\$ 76.0	\$ 79.0	\$ 76.0	\$ 79.0

(Unaudited, per diluted share)	Previous 2017 Outlook		Current 2017 Outlook	
	Low	High	Low	High
EPS from continuing operations	\$ 1.33	\$ 1.59	\$ 1.12	\$ 1.29
Foreign exchange impact	—	—	(0.05)	(0.05)
Strategic investments	0.06	0.04	0.46	0.44
SEC / FCPA matters and related costs	0.07	0.04	0.07	0.05
International restructuring	0.05	0.03	0.04	0.04
Legal judgments/settlements	—	—	0.01	0.01
Long-term income tax rate adjustment	(0.03)	(0.12)	(0.17)	(0.20)
Adjusted EPS from continuing operations	\$ 1.48	\$ 1.58	\$ 1.48	\$ 1.58
Weighted average number of diluted common shares	18,400,000	18,400,000	18,400,000	18,400,000

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 income (expense), net; income tax expense; and depreciation and amortization to net income (loss) from continuing operations. EBITDA provides management with additional insight to its results of operations.

Adjusted EBITDA, Adjusted Net Income from Continuing Operations and Adjusted Earnings per Share from Continuing Operations

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
- *Foreign exchange impact* – gains and losses related to foreign currency transactions; guidance presented does not include the impact of any future foreign exchange fluctuations
- *Strategic investments* – costs related to our strategic investments, including our investment in eNeura, Inc.
- *SEC / FCPA matters and related costs* – legal and other professional fees associated with the SEC Investigation, Securities Class Action Complaint and Brazil subsidiary compliance review
- *Infrastructure investments* – costs associated with our multi-year process and systems improvement effort, "Bluecore," which was completed in 2016
- *Legal judgments/settlements* – adverse or favorable legal judgments or negotiated legal settlements
- *International restructuring* – costs related to a planned restructuring, primarily consisting of severance charges and the write-down of certain assets
- *Long-term income tax rate adjustment* – reflects management's expectation of a long-term normalized effective tax rate of 38%, which is based on current tax law and current expected income; actual tax expense will ultimately be based on GAAP performance and may differ from the 38% effective tax rate due to a variety of factors, including the jurisdictions in which profits are determined to be earned and taxed, the resolutions of issues arising from tax audits with various tax authorities, and the ability to realize deferred tax assets

Net Margin

Net margin is a non-GAAP financial measure, which is calculated by subtracting sales and marketing from gross profit. Net margin is the primary metric used by our Chief Operating Decision Maker in managing our business.

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 International N.V.