

ORTHOFIX INTERNATIONAL N V

FORM 8-K (Current report filing)

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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): January 9, 2018

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: 599-9-4658525

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 January 9, 2018, Orthofix International N.V. (the “Company”) issued a press release announcing, among other things, its preliminary unaudited net sales for the fiscal quarter and year ended December 31, 2017. A copy of the press release is furnished herewith as Exhibit 99.1 and attached hereto.

Item 7.01. Regulation FD Disclosure.

As previously announced, the Company’s President and Chief Executive Officer, Brad Mason, will provide an investor presentation at 8:30 a.m. Pacific Time on Thursday, January 11, 2018, at the J.P. Morgan Healthcare Conference in San Francisco. A live audio webcast will be available on the Company’s website at ir.orthofix.com/events.cfm .

Item 9.01 . Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated January 9, 2018.

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: January 9, 2018



Orthofix Announces Preliminary 2017 Fourth Quarter and Full Year Net Sales Results
Provides 2018 Net Sales Guidance

LEWISVILLE, Texas — January 9, 2018 — Orthofix International N.V. (NASDAQ:OFIX), a global medical device company focused on musculoskeletal healing products and value-added services, today announced preliminary unaudited fourth quarter 2017 net sales of approximately \$117 million. These preliminary results represent reported sales growth of 7.7% and constant currency sales growth of 6.1% over the fourth quarter 2016. For the full year 2017, preliminary unaudited net sales were approximately \$434 million, an increase of 5.9% on a reported basis and 5.5% on a constant currency basis over the full year 2016.

Three Months Ended December 31,					
(Unaudited, U.S. Dollars, in millions)	2017	2016	Reported Change	Constant Currency Change	
BioStim	\$ 49.8	\$ 47.8	4.1%	4.1%	
Extremity Fixation	29.1	26.8	8.4%	2.2%	
Spine Fixation	21.2	18.7	13.5%	13.2%	
Biologics	16.8	15.2	10.7%	10.7%	
Total net sales	\$ 116.9	\$ 108.5	7.7%	6.1%	

Year Ended December 31,					
(Unaudited, U.S. Dollars, in millions)	2017	2016	Reported Change	Constant Currency Change	
BioStim	\$ 185.9	\$ 176.6	5.3%	5.3%	
Extremity Fixation	103.2	102.7	0.5%	(0.9)%	
Spine Fixation	82.0	72.6	12.8%	12.7%	
Biologics	62.7	57.9	8.3%	8.3%	
Total net sales	\$ 433.8	\$ 409.8	5.9%	5.5%	

As of December 31, 2017, cash and cash equivalents were approximately \$81 million compared to \$40 million as of December 31, 2016.

“In 2017 our strategy was to accelerate our organic topline growth rate while maintaining Adjusted EBITDA margins. This strategy proved very effective and resulted in us far exceeding our growth expectations for the year. Now as we look forward to 2018 and beyond, we are focused on continuing our organic growth momentum, expanding margins and actively pursuing value-accretive inorganic opportunities to further accelerate growth,” said Brad Mason, President and Chief Executive Officer.

“The keys to maintaining our organic sales momentum are, first and foremost, continuing our initiatives to further engage our legacy sales force and add new representation in under-served markets. The second key is to remain committed to investing in R&D and our rapid pace of new product introductions and value-added processes and services, such as our STIM onTrack Ô mobile app and JuniOrtho Ô pediatric care support tools. Lastly, we must educate physicians and payers through published, peer-reviewed research papers that demonstrate the safety, efficacy and cost-effectiveness of our products.

“While 2017 was a year to invest in accelerating our top-line growth rate, we can now return our focus to Adjusted EBITDA margin expansion. Our biggest opportunity is in gross margins, particularly around improving inventory and instrument set management in our Spine and Extremity Fixation businesses. We also expect to begin to realize the cost benefits of our restructuring initiatives as well as benefit from leveraging our fixed costs in SG&A.

“Lastly, Orthofix is very well positioned to grow through the acquisition of products, technologies and companies. In addition to our strong balance sheet and free cash flow, we have an experienced and proven management team, a global footprint and a

reconstructed infrastructure on which to build. We have been and will remain very active in pursuing opportunities of all sizes that will drive shareholder value. However, we will remain disciplined in our investment decisions, focusing on strategic fit, near-term cash EPS accretion and ROIC.

“We are pleased with our positioning going into 2018 and optimistic about our ability to drive shareholder value for the foreseeable future.”

2018 Outlook

For the full year 2018, the Company expects to report net sales of \$450 million to \$455 million based on current foreign exchange rates, which reflects reported growth of approximately 4% to 5%. This guidance includes a positive currency impact of approximately \$4.0 million, offset by an estimated \$4.0 million decrease in the 2018 marketing services fee the Company receives from MTF Biologics. This decrease is due to the final contractual step-down in the fee that Orthofix receives from MTF Biologics for our sales of Trinity ELITE[®] and Trinity Evolution[®] from 65% to 60%. This change, effective March 2018 in accordance with the terms of our amended 2008 agreement with MTF Biologics, coincides with the expiration of a corresponding royalty payment on our net sales of Trinity ELITE and Trinity Evolution that Orthofix currently pays to a third party. The expiration of the royalty payment substantially offsets the impact of the fee reduction to Operating Income and Adjusted EBITDA.

This 2018 net sales guidance reflects the new required revenue recognition standard that is required as of January 1, 2018. One of the primary impacts of this new standard is the timing of revenue recognition for our sales to stocking distributors that were historically accounted for using the sell-through method. This revenue will now be recorded on invoiced sales instead of deferring recognition until cash is received. While we expect that the new revenue recognition standard will provide a materially consistent revenue result on an annual basis as compared to our current revenue recognition policies, there may be some variability on a quarterly basis.

U.S. Tax Changes – Estimated Impact

The recent lowering of the U.S. corporate tax rate from 35% to 21% requires a revaluation of our U.S. deferred tax assets and liabilities. The Company expects to recognize a one-time, non-cash tax charge of \$8 million - \$12 million in the fourth quarter of 2017 related to this change. The new U.S. tax legislation is subject to a number of complex provisions, which we are currently reviewing. We will provide an update when we announce our fourth quarter and full year 2017 financials.

Upcoming Presentations / Conference Calls

As previously announced, the Company’s President and Chief Executive Officer, Brad Mason, will provide an investor presentation at 8:30 a.m. Pacific Time on Thursday, January 11, 2018, at the J.P. Morgan Healthcare Conference in San Francisco. A live audio webcast will be available on the Company’s website at www.orthofix.com by clicking on the Investors tab and then clicking the link on the Events and Presentations page.

The Company also expects to host a conference call in late February to discuss final fourth quarter and full year 2017 financial results and further discuss our outlook for 2018.

Non-GAAP Measures:

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.

Adjusted EBITDA

Adjusted EBITDA (earnings before interest income (expense), net; income tax expense; and depreciation and amortization) is a non-GAAP financial measure, which is calculated by adjusting EBITDA by certain items such as share-based compensation, foreign exchange impact, strategic investments, SEC/FCPA matters and related costs, infrastructure investments, legal judgments/settlements, charges related to U.S. Government resolutions, restructuring, succession charges and long-term income tax rate.

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 share-based compensation, do not directly impact cash flows, but are part of total compensation costs accounted for under GAAP.

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

We compensate for the limitations of our non-GAAP financial measures by relying upon GAAP results to gain a complete picture of our performance. The GAAP results provide 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.

About Orthofix

Orthofix International N.V. is a global medical device company focused on musculoskeletal healing products and value-added services. The Company's mission is to improve patients' lives by providing superior reconstruction and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, Texas, the Company has four strategic business units: BioStim, Extremity Fixation, Spine Fixation, and Biologics. Orthofix products are widely distributed 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 projections, financial condition, results of operations and businesses of Orthofix and its subsidiaries, are based on 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: the expected sales of our products, including recently launched products; the geographic concentration of certain of our sales and accounts receivable in countries or territories that are facing severe fiscal challenges; unanticipated expenditures; changing relationships with customers, suppliers, strategic partners and lenders; changes to and the interpretation of governmental regulations; risks relating to the protection of intellectual property; changes to the reimbursement policies of third parties; the impact of competitive products; changes to the competitive environment; the acceptance of new products in the market; conditions of the orthopedic and spine industry; credit markets and the global economy; corporate development and market development activities, including acquisitions or divestitures; unexpected costs or operating unit performance related to recent or future acquisitions; and other risks described in the "Risk Factors" section of our 2016 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.

Company Contact

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