

# ORTHOFIX INTERNATIONAL N V

## **FORM 10-Q** (Quarterly Report)

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Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(Mark one)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2017

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 0-19961



**ORTHOFIX INTERNATIONAL N.V.**

(Exact name of registrant as specified in its charter)

**Curaçao**

(State or other jurisdiction of  
incorporation or organization)

**7 Abraham de Veerstraat**

**Curaçao**

(Address of principal executive offices)

**98-1340767**

(I.R.S. Employer  
Identification No.)

**Not applicable**

(Zip Code)

**599-9-4658525**

(Registrant's telephone number, including area code)

**Not applicable**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer

Non-Accelerated filer  (Do not check if a smaller reporting company)

Accelerated filer

Smaller Reporting Company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

As of May 1, 2017, 18,044,335 shares of common stock were issued and outstanding.

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### Forward-Looking Statements

This report 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.

### Trademarks

Solely for convenience, our trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**ORTHOFIX INTERNATIONAL N.V.  
Condensed Consolidated Balance Sheets**

(U.S. Dollars, in thousands, except share data)	March 31, 2017 (Unaudited)	December 31, 2016
<b>Assets</b>		
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
<b>Total current assets</b>	<b>186,844</b>	<b>194,373</b>
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
<b>Total assets</b>	<b>\$ 354,745</b>	<b>\$ 372,103</b>
<b>Liabilities and shareholders' equity</b>		
Current liabilities		
Accounts payable	\$ 16,555	\$ 14,353
Other current liabilities	46,316	69,088
<b>Total current liabilities</b>	<b>62,871</b>	<b>83,441</b>
Other long-term liabilities	24,740	25,185
<b>Total liabilities</b>	<b>87,611</b>	<b>108,626</b>
Contingencies (Note 6)		
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)
<b>Total shareholders' equity</b>	<b>267,134</b>	<b>263,477</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 354,745</b>	<b>\$ 372,103</b>

*The accompanying notes form an integral part of these condensed consolidated financial statements*

**ORTHOFIX INTERNATIONAL N.V.**
**Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)**

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended March 31,	
	2017	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 (Note 6)		
Loss from discontinued operations	(527)	(990)
Income tax benefit	181	254
Net loss from discontinued operations	(346)	(736)
<b>Net income (loss)</b>	<b>\$ (2,654)</b>	<b>\$ 3,840</b>
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)
<b>Net income (loss) per common share—basic</b>	<b>\$ (0.15)</b>	<b>\$ 0.21</b>
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)
<b>Net income (loss) per common share—diluted</b>	<b>\$ (0.15)</b>	<b>\$ 0.20</b>
Weighted average number of common shares:		
Basic	17,979,675	18,477,881
Diluted	17,979,675	18,758,751
Other comprehensive income, before tax		
Unrealized gain on derivative instrument	–	48
Unrealized loss on debt securities	(3,220)	(824)
Reclassification adjustment for loss on debt securities in net income	5,585	–
Currency translation adjustment	234	1,221
Other comprehensive income before tax	2,599	445
Income tax related to items of other comprehensive loss	(900)	275
Other comprehensive income, net of tax	1,699	720
<b>Comprehensive income (loss)</b>	<b>\$ (955)</b>	<b>\$ 4,560</b>

The accompanying notes form an integral part of these condensed consolidated financial statements

**ORTHOFIX INTERNATIONAL N.V.**  
**Condensed Consolidated Statements of Cash Flows**

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended March 31,	
	2017	2016
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ (2,654)	\$ 3,840
Adjustments to reconcile net income (loss) to net cash from operating activities		
Depreciation and amortization	5,075	4,873
Amortization of debt costs and other assets	360	187
Provision for doubtful accounts	532	709
Deferred income taxes	5,074	953
Share-based compensation	2,816	2,099
Other-than-temporary impairment on debt securities	5,585	—
Other	242	1,340
Changes in operating assets and liabilities		
Restricted cash	14,369	—
Accounts receivable	(2,074)	3,927
Inventories	(2,750)	(1,937)
Prepaid expenses and other current assets	(203)	725
Accounts payable	1,014	(3,352)
Other current liabilities	(23,253)	(8,894)
Other long-term assets and liabilities	(663)	176
<b>Net cash from operating activities</b>	<b>3,470</b>	<b>4,646</b>
<b>Cash flows from investing activities</b>		
Capital expenditures for property, plant and equipment	(3,721)	(6,083)
Capital expenditures for intangible assets	(184)	(316)
Other investing activities	474	(1,000)
<b>Net cash from investing activities</b>	<b>(3,431)</b>	<b>(7,399)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common shares	3,876	5,756
Payments related to withholdings for share-based compensation	(2,079)	(1,014)
Repurchase and retirement of common shares	—	(26,464)
<b>Net cash from financing activities</b>	<b>1,797</b>	<b>(21,722)</b>
Effect of exchange rate changes on cash	244	658
Net change in cash and cash equivalents	2,080	(23,817)
Cash and cash equivalents at the beginning of the period	39,572	63,663
<b>Cash and cash equivalents at the end of the period</b>	<b>\$ 41,652</b>	<b>\$ 39,846</b>

*The accompanying notes form an integral part of these condensed consolidated financial statements*

**Business and basis of presentation**

Orthofix International N.V. (the “Company”) is a diversified, global medical device company focused on improving patients’ lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians. The Company has four strategic business units (“SBUs”) that are also its reporting segments: BioStim, Biologics, Extremity Fixation, and Spine Fixation.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair statement have been included. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes contained in the Company’s Form 10-K for the year ended December 31, 2016. Operating results for the three months ended March 31, 2017 are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2017.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates including those related to revenue recognition, contractual allowances, doubtful accounts, inventories, potential goodwill and intangible asset impairment, fair value measurements, litigation and contingent liabilities, income taxes, and share-based compensation. Actual results could differ from these estimates.

**1. Recently issued accounting pronouncements**

<b>Topic</b>	<b>Description of Guidance</b>	<b>Effective Date</b>	<b>Status of Company's Evaluation</b>
Revenue Recognition (ASU 2014-09, as amended)	Requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. Applied either retrospectively or as a cumulative effect adjustment as of the adoption date.	January 1, 2018	The Company is continuing to evaluate the impact this ASU will have on its consolidated financial statements and disclosures. The Company completed an initial impact assessment and believes adopting this ASU will materially impact the timing of revenue recognition, primarily for implant product sales to stocking distributors, which are currently accounted for using the sell-through method. Specifically, the Company believes the revenue associated with these sales will be recorded at the time of the sale instead of deferring recognition until cash is received. The Company expects to adopt this new guidance using the modified retrospective transition method.
Financial Instruments (ASU 2016-01)	Requires entities to measure equity investments, except in limited circumstances, at fair value and recognize any changes in fair value in net income. Applied prospectively.	January 1, 2018	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.
Leases (ASU 2016-02)	Requires a lessee to recognize lease assets and lease liabilities for leases classified as operating leases. Applied using a modified retrospective approach.	January 1, 2019	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements; however, the Company expects this guidance will result in current operating lease obligations being reflected on the consolidated balance sheet.



Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Income Taxes (ASU 2016-16)	Reduces complexity by requiring current and deferred income taxes for intra-entity asset transfers, other than inventory, to be recognized when the transfer occurs. Applied using a modified retrospective approach.	January 1, 2018	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.
Statement of Cash Flows (ASU 2016-18)	Reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. Applied retrospectively.	January 1, 2018	The Company is currently evaluating the impact this ASU may have on its consolidated statement of cash flows.

## 2. Inventories

Inventories were as follows:

(U.S. Dollars, in thousands)	March 31, 2017	December 31, 2016
Raw materials	\$ 3,966	\$ 7,978
Work-in-process	11,564	9,505
Finished products	47,109	42,434
Deferred cost of sales	3,632	3,429
	\$ 66,271	\$ 63,346

## 3. Other current liabilities

In December 2016, the Company approved and initiated a planned restructuring, which primarily affects the Extremity Fixation SBU, to streamline costs, improve operational performance, and wind down a non-core business. The restructuring plan consists primarily of severance charges and the write-down of certain assets. The Company expects to incur total pre-tax expense of approximately \$2.8 million in connection with this restructuring activity and has incurred cumulative costs to date of \$1.7 million. The Company had an accrual of \$1.5 million as of December 31, 2016 in other current liabilities related to the planned restructuring. In the first quarter of 2017, the Company reduced its estimate of costs to be incurred by approximately \$0.2 million and made additional payments of \$0.2 million, resulting in an ending accrual of \$1.0 million as of March 31, 2017.

## 4. Long-term debt

As of March 31, 2017, the Company has not made any borrowings under its five year \$125 million secured revolving credit facility with JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lenders party thereto. The Company has also not made any borrowings on its €5.8 million (\$6.2 million) available line of credit in Italy at March 31, 2017. The Company is in compliance with all required financial covenants as of March 31, 2017.

## 5. Fair value measurements

The fair value of the Company's financial assets and liabilities measured on a recurring basis were as follows:

(U.S. Dollars, in thousands)	March 31, 2017				December 31, 2016
	Level 1	Level 2	Level 3	Total	Total
<b>Assets</b>					
Collective trust funds	\$ —	\$ 1,583	\$ —	\$ 1,583	\$ 1,584
Treasury securities	466	—	—	466	467
Certificates of deposit	—	—	—	—	468
Debt securities	—	—	9,000	9,000	12,220
<b>Total</b>	<b>\$ 466</b>	<b>\$ 1,583</b>	<b>\$ 9,000</b>	<b>\$ 11,049</b>	<b>\$ 14,739</b>
<b>Liabilities</b>					
Deferred compensation plan	\$ —	\$ (1,207)	\$ —	\$ (1,207)	\$ (1,452)
<b>Total</b>	<b>\$ —</b>	<b>\$ (1,207)</b>	<b>\$ —</b>	<b>\$ (1,207)</b>	<b>\$ (1,452)</b>

The fair value of the debt security, which is recorded within other long-term assets, is based upon significant unobservable inputs, including the use of a discounted cash flow model, requiring the Company to develop its own assumptions; therefore, the Company has categorized this asset as a Level 3 financial asset. As of March 31, 2017, the Company revised its estimate of fair value based on current financial information and other assumptions, resulting in a fair value of \$9.0 million, a decrease of \$3.2 million during the first quarter of 2017.

The Company evaluated the decline in fair value to determine if the impairment was other-than-temporary. Based on this evaluation, the Company recorded an other-than-temporary impairment charge of \$5.6 million before income taxes, which is recorded in other expense. In addition to the decrease in fair value, the other-than-temporary impairment includes a reclassification of the amount that was previously considered temporary and included in accumulated other comprehensive loss.

The following table provides a reconciliation of the beginning and ending balances for debt securities measured at fair value using significant unobservable inputs (Level 3):

(U.S. Dollars, in thousands)	2017	2016
Balance at January 1	\$ 12,220	\$ 12,658
Accrued interest income	—	316
Gains or losses recorded for the period		
Recognized in net income	(5,585)	—
Recognized in other comprehensive income	2,365	(824)
Balance at March 31	\$ 9,000	\$ 12,150

## 6. Contingencies

In addition to the matters described below, in the normal course of its business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies. The Company believes losses with respect to these additional matters are individually and collectively immaterial as to a possible loss and range of loss.

### January 2017 SEC Settlements

In January 2017, the U.S. Securities and Exchange Commission (the "SEC") approved the Company's offers of settlement in connection with the SEC's investigations of accounting matters leading to the Company's prior restatement of financial statements and the Company's review of improper payments with respect to its subsidiary in Brazil. Both investigations were initiated in 2013 and involved matters self-reported to the SEC by the Company. The settlements approved by the SEC resolved these two matters, and included payments by the Company to the SEC of amounts previously accrued and funded into escrow by the Company during 2016. In connection with the Brazil-related settlement, the Company agreed to retain an independent compliance consultant for one year to review and test the Company's compliance program related to the U.S. Foreign Corrupt Practices Act.

*Discontinued Operations – Matters Related to Breg and Possible Indemnification Obligations*

On May 24, 2012, the Company sold Breg to an affiliate of Water Street Healthcare Partners II, L.P. (“Water Street”). Under the terms of the agreement, the Company indemnified Water Street and Breg with respect to certain specified matters, including the following:

- Breg was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008. Since 2008, numerous product liability cases have been filed in the United States alleging that the local anesthetic, when dispensed by such infusion pumps inside a joint, causes a rare arthritic condition called “chondrolysis.” One case remains outstanding for which the Company currently cannot reasonably estimate the possible loss, or range of loss.
- At the time of its divestiture by the Company, Breg was engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases have been filed in recent years, mostly in California state court. In September 2014, the Company entered into a master settlement agreement resolving then pending pre-close cold therapy claims. Currently pending is a cold therapy claim in which the California Supreme Court recently denied a plaintiff’s request for review resulting in the plaintiff consenting to the California Court of Appeal’s proposed reduction of an adverse July 2012 jury verdict, and a post-close cold therapy claim pending in California state court. As of March 31, 2017, the Company has an accrual of \$2.4 million recorded within other current liabilities; however, the actual liability could be higher or lower than the amount accrued.

Charges incurred as a result of this indemnification are reflected as discontinued operations in the condensed consolidated statements of operations.

**7. Accumulated other comprehensive loss**

The components of and changes in accumulated other comprehensive loss were as follows:

(U.S. Dollars, in thousands)	Currency Translation Adjustments	Debt Securities	Accumulated Other Comprehensive Loss
Balance at December 31, 2016	\$ (5,115)	\$ (1,465)	\$ (6,580)
Other comprehensive income (loss)	234	(3,220)	(2,986)
Income taxes	—	1,223	1,223
Reclassification adjustments to:			
Other expense, net	—	5,585	5,585
Income taxes	—	(2,123)	(2,123)
Balance at March 31, 2017	\$ (4,881)	\$ —	\$ (4,881)

**8. Business segment information**

The table below present net sales, which includes product sales and marketing service fees, by reporting segment:

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

The primary metric used in managing the Company is net margin, which the Company defines as gross profit less sales and marketing expense. The table below presents net margin by reporting segment:

(U.S. Dollars, in thousands)	Three Months Ended March 31,	
	2017	2016
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
General and administrative	18,282	17,005
Research and development	7,424	7,640
Operating income	\$ 5,919	\$ 7,075

## 9. Share-based compensation

The following tables present the detail of share-based compensation by line item in the condensed consolidated statements of operations as well as by award type:

(U.S. Dollars, in thousands)	Three Months Ended March 31,	
	2017	2016
Cost of sales	\$ 149	\$ 117
Sales and marketing	360	276
General and administrative	2,102	1,558
Research and development	205	148
	\$ 2,816	\$ 2,099

(U.S. Dollars, in thousands)	Three Months Ended March 31,	
	2017	2016
Stock options	\$ 595	\$ 475
Time-based restricted stock awards	1,292	1,308
Performance-based restricted stock awards	112	—
Performance-based and market-based restricted stock units	466	—
Stock purchase plan	351	316
	\$ 2,816	\$ 2,099

During the three months ended March 31, 2017 and 2016, the Company issued 214,679 and 203,398 shares, respectively, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

## 10. Income taxes

Income tax provisions for interim periods are based on an estimated annual income tax rate, adjusted for discrete tax items. As a result, the Company's interim effective tax rates may vary significantly from the statutory tax rate and the annual effective tax rate.

For the three months ended March 31, 2017 and 2016, the effective tax rate on continuing operations was 242.8% and 48.4%, respectively. The primary factors affecting the Company's effective tax rate for the three months ended March 31, 2017, were the method for estimating income taxes at interim periods, the mix of earnings among tax jurisdictions and current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit.

The Internal Revenue Service is currently conducting examinations of the Company's federal income tax returns for 2012 and 2013. The Company cannot reasonably determine if these examinations will have a material impact on its financial statements and cannot predict the timing regarding resolution of these tax examinations.

## 11. Earnings per share ("EPS")

For the three months ended March 31, 2017 and 2016, no adjustments were made to net income (loss) for purposes of calculating basic and diluted EPS. The following is a reconciliation of the weighted average shares used in diluted EPS computations.

	Three Months Ended March 31,	
	2017	2016
Weighted average common shares-basic	17,979,675	18,477,881
Effect of dilutive securities		
Unexercised stock options and stock purchase plan	—	138,292
Unvested time-based restricted stock awards	—	142,578
Weighted average common shares-diluted	17,979,675	18,758,751

There were 1,019,185 and 387,396 outstanding options, restricted stock, and performance-based or market-based equity awards not included in the diluted earnings per share computation for the three months ended March 31, 2017 and 2016, respectively, because inclusion of these awards was anti-dilutive or, for performance-based and market-based awards, all necessary conditions had not been satisfied by the end of the respective period.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of our operations should be read in conjunction with the "Forward-Looking Statements" and our condensed consolidated financial statements and related notes thereto appearing elsewhere in this Form 10-Q.

### Executive Summary

We are 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, we have four strategic business units ("SBUs") that are also our reporting segments: BioStim, Biologics, Extremity Fixation and Spine Fixation. Our products are widely distributed by our sales representatives and distributors.

Notable highlights and achievements in the first quarter of 2017 include the following:

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

### Results of Operations

The following table presents certain items in our condensed consolidated statements of operations as a percent of net sales:

	Three Months Ended March 31,	
	2017 (%)	2016 (%)
Gross profit	78.0	77.6
Sales and marketing	47.2	45.4
General and administrative	17.8	17.3
Research and development	7.2	7.7
Operating income	5.8	7.2
Net income (loss) from continuing operations	(2.2)	4.6

### Net Sales by Strategic Business Unit

The following table presents net sales by SBU:

(U.S. Dollars, in thousands)	Three Months Ended March 31,		Percentage Change	
	2017	2016	Reported	Constant Currency
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%

## BioStim

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BioStim manufactures, distributes, and provides support services of market leading devices that enhance bone fusion. BioStim uses distributors and sales representatives to sell its devices to hospitals, doctors, other healthcare providers, and patients.

Net sales increased \$3.5 million, or 8.5%, due to an expanding prescribing physician base driven by the supportive NASS coverage recommendations and the launch of our next generation products.

## Biologics

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Biologics provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. Biologics markets its tissues primarily in the U.S. through a network of distributors and independent sales representatives to supply to hospitals, doctors, and other healthcare providers.

Net sales increased \$0.9 million or 6.3%

- Increase in volume for our Trinity products driven by the addition of new distributors over the past twelve months
- Partially offset by a low single-digit reduction in average selling price for our Trinity products resulting from increased competition

## Extremity Fixation

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Extremity Fixation offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. Extremity Fixation distributes its products globally through a network of distributors and sales representatives to sell orthopedic products to hospitals, doctors, and other health providers.

Net sales decreased \$0.8 million or 3.1%

- Includes the negative impact from both foreign currency translation and the divestiture of a non-core business in the United Kingdom; on a constant currency basis and excluding the non-core business divestiture, net sales increased \$0.2 million, or 0.7%
- Decrease in year-over-year cash collections for the quarter of 25% from international distributors whose revenue is recognized upon cash receipt
- Partially offset by growth in the U.S., largely due to the continued adoption of our TL-HEX product line

## Spine Fixation

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Spine Fixation specializes in the design, development and marketing of a broad portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products globally through a network of distributors and sales representatives to sell spine products to hospitals, doctors and other healthcare providers.

Net sales increased \$0.4 million or 2.3%

- Increase in U.S. sales of 12% due to improved distributor engagement, the addition of new distributor partners in the last several quarters, and the uptake of recent product introductions
- Partially offset by a decrease in year-over-year cash collections for the quarter of 28% from international distributors whose revenue is recognized upon cash receipt

## Net Margin

(U.S. Dollars, in thousands)	Three Months Ended March 31,		
	2017	2016	% Change
Gross profit	\$ 80,157	\$ 76,542	4.7%
Sales and marketing	(48,532)	(44,822)	8.3%
Net margin	\$ 31,625	\$ 31,720	-0.3%
Gross margin	78.0%	77.6%	0.4%
Net margin	30.8%	32.1%	-1.3%

Net margin, a non-GAAP financial measure, which is calculated by subtracting sales and marketing expense from gross profit, decreased \$0.1 million

- Gross profit increased \$3.6 million, primarily due to the growth in net sales and increase in sales mix for our regenerative products, which have higher margins as compared to our fixation products.
- Sales and marketing expense increased \$3.7 million, primarily due to an increase in compensation expense, including commissions, as we had a higher mix of sales in our Biologics and Spine Fixation SBU from new distributors, who typically receive higher commission rates in their first year.

The following table presents net margin by SBU. The reasons for the changes in net margin by SBU are generally consistent with the information provided above for gross profit and sales and marketing expense.

(U.S. Dollars, in thousands)	Three Months Ended March 31,		
	2017	2016	% Change
BioStim	\$ 17,133	\$ 16,408	4.4%
Biologics	6,171	6,104	1.1%
Extremity Fixation	6,412	7,175	-10.6%
Spine Fixation	2,007	2,335	-14.0%
Corporate	(98)	(302)	-67.5%
Net margin	\$ 31,625	\$ 31,720	-0.3%

## General and Administrative Expense

(U.S. Dollars, in thousands)	Three Months Ended March 31,		
	2017	2016	% Change
General and administrative	\$ 18,282	\$ 17,005	7.5%
As a percentage of net sales	17.8%	17.3%	0.5%

General and administrative expense increased \$1.3 million

- Increase in professional fees of \$1.0 million, largely due to increased spend in 2017 related to strategic investments, partially offset by the completion of Project Bluecore in 2016
- Increase in share-based compensation expense of \$0.5 million related to performance-based and market-based awards
- Increase in depreciation expense of \$0.5 million, largely associated with the completion of certain Project Bluecore initiatives

## Research and Development Expense

(U.S. Dollars, in thousands)	Three Months Ended March 31,		
	2017	2016	% Change
Research and development	\$ 7,424	\$ 7,640	-2.8%
As a percentage of net sales	7.2%	7.7%	-0.5%



Research and development expense decreased \$0.2 million

- Decrease of \$1.3 million due to an investment made in the first quarter of 2016 to expand the processing and storage capabilities of MTF, the supplier of our Trinity Evolution and Trinity ELITE tissue forms
- Partially offset by increased costs of \$1.0 million associated with clinical trials underway to identify potential new clinical indications for our PEMF technology

#### **Non-operating Income and Expense**

In 2017, we recorded an other-than-temporary impairment on the eNeura debt security of \$5.6 million before income taxes. For additional discussion see Note 5 to the Notes to the Unaudited Condensed Consolidated Financial Statements.

#### **Income Taxes**

(U.S. Dollars, in thousands)	Three Months Ended March 31,		
	2017	2016	% Change
Income tax expense	\$ 3,924	\$ 4,294	-8.6%
Effective tax rate	242.8%	48.4%	194.4%

The increase in the effective tax rate was primarily a result of a decrease in income before taxes, largely driven by the other-than-temporary impairment on the eNeura debt security. The primary factors affecting our effective tax rate for the first quarter of 2017 are as follows:

- The mix of earnings among tax jurisdictions
- Current period losses in jurisdictions where we do not currently receive a tax benefit

#### **Liquidity and Capital Resources**

Cash and cash equivalents at March 31, 2017, were \$41.7 million compared to \$39.6 million at December 31, 2016.

(U.S Dollars, in thousands)	Three Months Ended March 31,		
	2017	2016	Change
Net cash from operating activities	\$ 3,470	\$ 4,646	\$ (1,176)
Net cash from investing activities	(3,431)	(7,399)	3,968
Net cash from financing activities	1,797	(21,722)	23,519
Effect of exchange rate changes on cash	244	658	(414)
Net change in cash and cash equivalents	\$ 2,080	\$ (23,817)	\$ 25,897

The following table presents free cash flow, a non-GAAP financial measure, which is calculated by subtracting capital expenditures from net cash from operating activities.

(U.S Dollars, in thousands)	Three Months Ended March 31,		
	2017	2016	Change
Net cash from operating activities	\$ 3,470	\$ 4,646	\$ (1,176)
Capital expenditures	(3,905)	(6,399)	2,494
Free cash flow	\$ (435)	\$ (1,753)	\$ 1,318

#### **Operating Activities**

Cash flows from operating activities decreased \$1.2 million

- Decrease in net income of \$6.5 million
- Net increase of \$9.5 million for non-cash gains and losses, largely related to the other-than-temporary impairment on the eNeura debt security and deferred income tax expense

- Net decrease of \$4.2 million relating to changes in working capital accounts, primarily attributable to changes in accounts receivable and accounts payable

Our two primary working capital accounts are accounts receivable and inventory. Days sales in receivables were 52 days at March 31, 2017 compared to 51 days at March 31, 2016. Inventory turns were 1.3 times as of March 31, 2017 compared to 1.5 times at March 31, 2016.

#### *U.S. Government Resolutions*

In January 2017, the U.S. Securities and Exchange Commission (the "SEC") approved our offers of settlement in connection with the SEC's investigations of accounting matters leading to our prior restatement of financial statements and our review of improper payments in Brazil. The settlements approved by the SEC resolved these two matters, and included payments to the SEC of amounts previously accrued and funded into escrow during 2016. For additional information, see Note 6 to the Notes to the Condensed Consolidated Financial Statements.

#### *Investing Activities*

Cash flows from investing activities increased \$4.0 million

- Increase of \$2.5 million related to reduced capital expenditures, largely as a result of completing Project Bluecore in 2016
- Increase of \$1.0 million from our additional investment in Bone Biologics, Inc. during 2016

#### *Financing Activities*

Cash flows from financing activities increased \$23.5 million

- Increase of \$26.5 million related to the share repurchase plan, which was completed in 2016
- Partially offset by a decrease in net proceeds of \$2.9 million from the issuance of common shares

#### *Credit Facilities*

There have been no material changes to our debt instruments as disclosed in our Form 10-K for the year ended December 31, 2016.

#### *Other*

For information regarding Contingencies, see Note 6 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

#### *Off-balance Sheet Arrangements*

As of March 31, 2017, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, cash flows, liquidity, capital expenditures or capital resources that are material to investors.

#### *Contractual Obligations*

There have been no material changes in any of our material contractual obligations as disclosed in our Form 10-K for the year ended December 31, 2016.

#### *Critical Accounting Estimates*

There have been no material changes to our critical accounting estimates, as described in our Form 10-K for the year ended December 31, 2016.

#### *Recently Issued Accounting Pronouncements*

See Note 1 of the Notes to the Unaudited Condensed Consolidated Financial Statements for detailed information regarding the status of recently issued accounting pronouncements.

## **Non-GAAP Financial Measures**

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. We believe it is important to provide investors with the same non-GAAP metrics used to supplement information regarding the performance and underlying trends of our business operations in order to facilitate comparisons to 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.

The non-GAAP financial measures used in this filing 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 that can have a material effect on cash flows.

### *Constant Currency*

Constant currency 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.

### *Net Margin*

Net margin is calculated by subtracting sales and marketing expense from gross profit. Net margin is the primary metric used by our Chief Operating Decision Maker in managing the business.

### *Free Cash Flow*

Free cash flow is calculated by subtracting capital expenditures from net cash 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.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

There have been no material changes to our market risks as disclosed in our Form 10-K for the year ended December 31, 2016.

## **Item 4. Controls and Procedures**

### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) designed to provide reasonable assurance that the information required to be disclosed in reports filed or submitted under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. These include controls and procedures designed to ensure that this information is accumulated and communicated to management, including our President and Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Management, with the participation of the President and Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2017. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that the disclosure controls and procedures were effective as of March 31, 2017.

### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

For information regarding legal proceedings, see Note 6 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein, which is incorporated by reference into this Part II, Item 1.

### **Item 1A. Risk Factors**

There have been no material changes to the risk factors disclosed in the "Risk Factors" section of our Form 10-K for the year ended December 31, 2016.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

We have not made any repurchases of our common stock during the first quarter of 2017.

### **Item 3. Defaults Upon Senior Securities**

Not applicable.

### **Item 4. Mine Safety Disclosures**

Not applicable.

### **Item 5. Other Information**

There are no matters to be reported under this heading.

**Item 6. Exhibits**

- 31.1\* Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
- 31.2\* Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
- 32.1\* Section 1350 Certifications of each of the Chief Executive Officer and Chief Financial Officer.
- 101\* The following materials from this Form 10-Q, formatted in Extensible Business Reporting Language (“XBRL”): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Condensed Consolidated Statements of Cash Flows and (iv) related notes, detail tagged.

\* Filed herewith.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORTHOFIX INTERNATIONAL N.V.

Date: May 4, 2017

By: /s/ BRADLEY R. MASON  
Name: Bradley R. Mason  
Title: President and Chief Executive Officer

Date: May 4, 2017

By: /s/ DOUG RICE  
Name: Doug Rice  
Title: Chief Financial Officer

## CERTIFICATION

I, Bradley R. Mason, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended March 31, 2017, of Orthofix International N.V.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 4, 2017

By:           /s/ BRADLEY R. MASON          

Name: Bradley R. Mason

Title: President and Chief Executive Officer

## CERTIFICATION

I, Doug Rice, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended March 31, 2017, of Orthofix International N.V.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 4, 2017

By: /s/ DOUG RICE

Name: Doug Rice

Title: Chief Financial Officer



**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Orthofix International N.V. ("Orthofix") on Form 10-Q for the quarterly period ended March 31, 2017, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, Bradley R. Mason, Chief Executive Officer and President of Orthofix, and Doug Rice, Chief Financial Officer, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Orthofix.

Dated: May 4, 2017

/s/ BRADLEY R. MASON

Name: Bradley R. Mason

Title: President and Chief Executive Officer

Dated: May 4, 2017

/s/ DOUG RICE

Name: Doug Rice

Title: Chief Financial Officer