

ORTHOFIX INTERNATIONAL N V

Form 10-Q

October 30, 2017

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 September 30, 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)

Edgar Filing: ORTHOFIX INTERNATIONAL N V - Form 10-Q

(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

7 Abraham de Veerstraat

Curaçao Not applicable  
(Address of principal executive offices) (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

Accelerated filer

Non-Accelerated filer (Do not check if a smaller reporting company) 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 October 27, 2017, 18,231,334 shares of common stock were issued and outstanding.

Table of Contents

	Page
<b>PART I <u>FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets as of September 30, 2017, and December 31, 2016</u>	4
<u>Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2017, and 2016</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and 2016</u>	6
<u>Notes to the Unaudited Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	21
Item 4. <u>Controls and Procedures</u>	21
<b>PART II <u>OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	23
Item 1A. <u>Risk Factors</u>	23
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
Item 3. <u>Defaults Upon Senior Securities</u>	23
Item 4. <u>Mine Safety Disclosures</u>	23
Item 5. <u>Other Information</u>	23
Item 6. <u>Exhibits</u>	24
<u>SIGNATURES</u>	25

## 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 terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2016 (the “2016 Form 10-K”). 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 the 2016 Form 10-K, 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

	September 30,	December 31,
(U.S. Dollars, in thousands, except share data)	2017	2016
	(Unaudited)	
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 53,925	\$ 39,572
Restricted cash	—	14,369
Accounts receivable, net of allowances of \$8,925 and \$8,396, respectively	61,187	57,848
Inventories	80,124	63,346
Prepaid expenses and other current assets	18,172	19,238
Total current assets	213,408	194,373
Property, plant and equipment, net	46,678	48,916
Patents and other intangible assets, net	9,915	7,461
Goodwill	53,565	53,565
Deferred income taxes	47,052	47,325
Other long-term assets	15,683	20,463
Total assets	\$ 386,301	\$ 372,103
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 13,352	\$ 14,353
Other current liabilities	60,718	69,088
Total current liabilities	74,070	83,441
Other long-term liabilities	26,920	25,185
Total liabilities	100,990	108,626
<b>Contingencies (Note 6)</b>		
<b>Shareholders' equity</b>		
Common shares \$0.10 par value; 50,000,000 shares authorized;		
18,212,916 and 17,828,155 issued and outstanding as of September 30,		
2017 and December 31, 2016, respectively	1,821	1,783
Additional paid-in capital	215,778	204,095
Retained earnings	68,834	64,179
Accumulated other comprehensive loss	(1,122 )	(6,580 )
Total shareholders' equity	285,311	263,477
Total liabilities and shareholders' equity	\$ 386,301	\$ 372,103

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

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Net sales	\$ 105,247	\$ 98,497	\$ 316,927	\$ 301,251
Cost of sales	23,717	19,880	69,475	64,533
Gross profit	81,530	78,617	247,452	236,718
Sales and marketing	47,493	41,717	146,496	132,582
General and administrative	18,068	19,272	56,759	54,822
Research and development	6,935	6,858	21,246	21,294
Charges related to U.S. Government resolutions	—	1,499	—	14,369
Operating income	9,034	9,271	22,951	13,651
Interest income (expense), net	(15 )	471	106	320
Other income (expense), net	479	(634 )	(3,284 )	1,346
Income before income taxes	9,498	9,108	19,773	15,317
Income tax benefit (expense)	(6,150 )	1,276	(13,998 )	(6,703 )
Net income from continuing operations	3,348	10,384	5,775	8,614
Discontinued operations (Note 6)				
Income (loss) from discontinued operations	65	(1,018 )	(1,762 )	(3,580 )
Income tax benefit	43	530	642	1,258
Net income (loss) from discontinued operations	108	(488 )	(1,120 )	(2,322 )
Net income	\$ 3,456	\$ 9,896	\$ 4,655	\$ 6,292
Net income (loss) per common share—basic				
Net income from continuing operations	\$ 0.18	\$ 0.57	\$ 0.32	\$ 0.47
Net income (loss) from discontinued operations	0.01	(0.02 )	(0.06 )	(0.13 )
Net income per common share—basic	\$ 0.19	\$ 0.55	\$ 0.26	\$ 0.34
Net income (loss) per common share—diluted				
Net income from continuing operations	\$ 0.18	\$ 0.56	\$ 0.31	\$ 0.46
Net income (loss) from discontinued operations	0.01	(0.02 )	(0.06 )	(0.12 )
Net income per common share—diluted	\$ 0.19	\$ 0.54	\$ 0.25	\$ 0.34
Weighted average number of common shares:				
Basic	18,180,845	18,091,650	18,071,093	18,238,533
Diluted	18,572,791	18,382,118	18,394,542	18,569,861
Other comprehensive income, before tax				
Unrealized gain (loss) on derivative instrument	—	(3 )	—	124
Unrealized gain (loss) on debt securities	—	4,703	(3,220 )	843
Reclassification adjustment for loss on debt securities in net income	—	—	5,585	—
Currency translation adjustment	1,111	820	3,993	1,471
Other comprehensive income before tax	1,111	5,520	6,358	2,438
Income tax related to items of other comprehensive loss	—	(1,694 )	(900 )	(354 )

Edgar Filing: ORTHOFIX INTERNATIONAL N V - Form 10-Q

Other comprehensive income, net of tax	1,111	3,826	5,458	2,084
Comprehensive income	\$4,567	\$13,722	\$10,113	\$8,376

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

5

---



## ORTHOFIX INTERNATIONAL N.V.

## Condensed Consolidated Statements of Cash Flows

(Unaudited, U.S. Dollars, in thousands)	Nine Months Ended	
	September 30, 2017	2016
<b>Cash flows from operating activities</b>		
Net income	\$4,655	\$6,292
<b>Adjustments to reconcile net income to net cash from operating activities</b>		
Depreciation and amortization	15,421	15,483
Amortization of debt costs and other assets	1,072	1,259
Provision for doubtful accounts	1,555	1,059
Deferred income taxes	153	1,246
Share-based compensation	9,124	12,154
Other-than-temporary impairment on debt securities	5,585	—
Other	823	663
<b>Changes in operating assets and liabilities</b>		
Restricted cash	14,369	—
Accounts receivable	(4,302 )	5,887
Inventories	(14,714)	(6,638 )
Prepaid expenses and other current assets	1,377	(568 )
Accounts payable	(2,233 )	(2,291 )
Other current liabilities	(11,639)	5,502
Other long-term assets and liabilities	2,248	(1,652 )
<b>Net cash from operating activities</b>	<b>23,494</b>	<b>38,396</b>
<b>Cash flows from investing activities</b>		
Capital expenditures for property, plant and equipment	(11,441)	(12,934)
Capital expenditures for intangible assets	(1,849 )	(1,327 )
Other investing activities	474	(3,613 )
<b>Net cash from investing activities</b>	<b>(12,816)</b>	<b>(17,874)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common shares	6,277	19,688
Payments related to withholdings for share-based compensation	(3,679 )	(2,354 )
Repurchase and retirement of common shares	—	(54,996)
<b>Net cash from financing activities</b>	<b>2,598</b>	<b>(37,662)</b>
Effect of exchange rate changes on cash	1,077	301
<b>Net change in cash and cash equivalents</b>	<b>14,353</b>	<b>(16,839)</b>
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>\$53,925</b>	<b>\$46,824</b>

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



## ORTHOFIX INTERNATIONAL N.V.

## Notes to the Unaudited 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 and nine months ended September 30, 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, 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

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
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	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 Extremity Fixation and Spine Fixation 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. Further, as a result of adopting ASU 2014-09, the

cumulative effect adjustment  
as of the adoption date.

Company expects to record a significant increase in accounts receivable and a decrease within inventories, with these changes offset by an adjustment to the Company's retained earnings balance on January 1, 2018, as a result of the changes in judgments. Adopting this guidance will also result in material changes to the Company's disclosures for revenue recognition and contracts with customers. The Company expects to adopt this new guidance using the modified retrospective transition method.

7

---

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
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, but based upon its initial assessment, the Company does not believe the adoption of this ASU will materially impact 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 materially impact the Company's consolidated balance sheet, resulting in current operating lease obligations being reflected on the consolidated balance sheet.
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 expected to adopt this ASU as of January 1, 2018, and believes that it will materially impact its consolidated statements of cash flows. Adoption of this ASU is expected to result in an increase in net cash from operating activities of \$14.4 million for the year ended December 31, 2016 and would have resulted in a decrease in net cash from operating activities of \$14.4 million for the nine months ended September 30, 2017 if this ASU had been early adopted.

## 2. Inventories

Inventories were as follows:

		December September 30,	31,
(U.S. Dollars, in thousands)	2017	2016	
Raw materials	\$ 5,269	\$ 7,978	
Work-in-process	12,322	9,505	
Finished products	58,964	42,434	
Deferred cost of sales	3,569	3,429	
	\$ 80,124	\$ 63,346	

3. Other current liabilities

In December 2016, the Company approved and initiated a planned restructuring, which primarily affects the Extremity Fixation SBU (the “Extremity Fixation restructuring plan”), to streamline costs, improve operational performance, and wind down a non-core business. The Extremity Fixation 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 \$3.1 million in connection with this restructuring activity and has incurred cumulative costs to date of \$2.4 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 nine months ended September 30, 2017, the Company incurred costs of

8

---

approximately \$0.5 million and made additional payments of \$1.6 million, resulting in an ending accrual of \$0.4 million as of September 30, 2017.

In September 2017, the Company approved and executed an additional restructuring plan, which primarily affects the entity's corporate shared services in the U.S. (the "U.S. restructuring plan"), to streamline costs and to improve operational performance. The U.S. restructuring plan consists primarily of severance charges. The Company estimates total pre-tax expense of approximately \$1.8 million in connection with this restructuring activity, all of which was incurred during the third quarter of 2017, and recorded within operating expenses. No payments were made as of September 30, 2017; therefore, \$1.8 million is accrued within other current liabilities at September 30, 2017.

#### 4. Long-term debt

As of September 30, 2017, the Company has not made any borrowings under the five year \$125 million secured revolving credit facility it entered into in August 2015 with JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lenders. The Company has also not made any borrowings on its €5.8 million (\$6.9 million) available line of credit in Italy at September 30, 2017. The Company is in compliance with all required financial covenants as of September 30, 2017.

#### 5. Fair value measurements

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

	September 30,			December 31,	
	2017		Level	2016	
(U.S. Dollars, in thousands)	Level 1	Level 2	3	Total	Total
<b>Assets</b>					
Collective trust funds	\$—	\$1,565	\$—	\$1,565	\$ 1,584
Treasury securities	522	—	—	522	467
Certificates of deposit	—	—	—	—	468
Debt security	—	—	9,000	9,000	12,220
Total	\$522	\$1,565	\$9,000	\$11,087	\$ 14,739
<b>Liabilities</b>					
Deferred compensation plan	\$—	\$(1,307)	\$—	\$(1,307)	\$(1,452)
Total	\$—	\$(1,307)	\$—	\$(1,307)	\$(1,452)

The Company holds a debt security of eNeura, Inc., a privately held medical technology company that is developing devices for the treatment of migraines. The debt security is further described in Note 6 to the financial statements contained within our Form 10-K for the year ended December 31, 2016. 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 September 30, 2017, the Company reassessed its estimate of fair value based on current financial information and other assumptions, resulting in a fair value of \$9.0 million, which is consistent with the Company's estimated fair value from the first and second quarters of 2017. This compares to an amortized cost basis in the debt security of \$18.4 million.

The Company evaluated the decline in fair value of the debt security, which was recorded during the first quarter of 2017, 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 included 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	—	969
Gains or losses recorded for the period		
Recognized in net income	(5,585 )	—
Recognized in other comprehensive income	2,365	843
Balance at September 30	\$9,000	\$ 14,470

## 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.

### 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.

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 were filed, 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 post-close cold therapy claim in California state court. As of September 30, 2017, the Company has an accrual of \$1.8 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.

### Expiration of Corporate Integrity Agreement with HHS-OIG

In May 2012, the Company entered into a five-year corporate integrity agreement (the “CIA”) with the Office of Inspector General of the Department of Health and Human Services (“HHS-OIG”), in connection with a U.S. government settlement. In October 2017, the Company received a letter from HHS-OIG confirming that the Company has satisfied its CIA requirements and that the CIA has expired.

## 7. Accumulated other comprehensive loss

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

(U.S. Dollars, in thousands)	Currency		Accumulated Other Comprehensive Loss
	Translation Adjustments	Debt Security	
Balance at December 31, 2016	\$ (5,115 )	\$ (1,465 )	\$ (6,580 )
Other comprehensive income (loss)	3,993	(3,220 )	773
Income taxes	—	1,223	1,223
Reclassification adjustments to:			
Other expense, net	—	5,585	5,585
Income taxes	—	(2,123 )	(2,123 )
Balance at September 30, 2017	\$ (1,122 )	\$ —	\$ (1,122 )

## 8. Revenue recognition

The table below presents net sales, which includes product sales and marketing service fees, for both the three and nine months ended September 30, 2017 and 2016.

(U.S. Dollars, in thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Product sales	\$90,645	\$84,997	\$272,954	\$261,490
Marketing service fees	14,602	13,500	43,973	39,761
Net sales	\$105,247	\$98,497	\$316,927	\$301,251

Product sales primarily consist of stimulation devices and fixation products. Marketing service fees are received from the Musculoskeletal Transplant Foundation (“MTF”) based on total sales of biologics tissues.

## 9. 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		
	September 30,		
	2017	2016	Change
BioStim	\$44,427	\$42,956	3.4 %
Biologics	15,218	14,335	6.2 %
Extremity Fixation	25,447	24,314	4.7 %
Spine Fixation	20,155	16,892	19.3 %
Net sales	\$105,247	\$98,497	6.9 %

(U.S. Dollars, in thousands)	Nine Months Ended		
	September 30,		
	2017	2016	Change
BioStim	\$136,140	\$128,758	5.7 %
Biologics	45,866	42,685	7.5 %
Extremity Fixation	74,139	75,840	-2.2 %
Spine Fixation	60,782	53,968	12.6 %

Edgar Filing: ORTHOFIX INTERNATIONAL N V - Form 10-Q

Net sales \$316,927 \$301,251 5.2 %

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

(U.S. Dollars, in thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
BioStim	\$18,285	\$19,996	\$54,887	\$54,980
Biologics	6,010	6,821	18,651	19,642
Extremity Fixation	7,723	8,834	20,901	24,170
Spine Fixation	2,122	1,388	6,825	5,925
Corporate	(103 )	(139 )	(308 )	(581 )
Non-GAAP net margin	\$34,037	\$36,900	\$100,956	\$104,136
General and administrative	18,068	19,272	56,759	54,822
Research and development	6,935	6,858	21,246	21,294
Charges related to U.S. Government resolutions	—	1,499	—	14,369
Operating income	\$9,034	\$9,271	\$22,951	\$13,651
Interest income (expense), net	(15 )	471	106	320
Other income (expense), net	479	(634 )	(3,284 )	1,346
Income before income taxes	\$9,498	\$9,108	\$19,773	\$15,317

## 10. 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:

	Three Months Ended		Nine Months Ended	
(U.S. Dollars, in thousands)	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Cost of sales	\$151	\$175	\$437	\$401
Sales and marketing	394	331	1,073	887
General and administrative	2,828	7,148	6,935	10,082
Research and development	259	488	679	784
	\$3,632	\$8,142	\$9,124	\$12,154

	Three Months Ended		Nine Months Ended	
(U.S. Dollars, in thousands)	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Stock options	\$684	\$425	\$1,802	\$1,367
Time-based restricted stock awards		1,552	1,840	4,083
Performance-based restricted stock awards		115	5,089	340
Performance-based and market-based restricted stock units		997	472	1,935
Stock purchase plan		284	316	964
		\$3,632	\$8,142	\$9,124
				\$12,154

The decreases in share-based compensation expense of \$4.5 million and \$3.0 million, respectively, for the three and nine months ended September 30, 2017, as compared to the prior period were primarily attributable to certain performance-based awards that were first determined to be probable to vest during the third quarter of 2016, resulting in additional expense of \$5.1 million during the third quarter of 2016.

During the three months ended September 30, 2017 and 2016, the Company issued 93,486 and 181,235 shares, respectively, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the nine months ended September 30, 2017 and 2016, the Company issued 384,761 and 710,026 shares, respectively, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

## 11. 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 September 30, 2017 and 2016, the effective tax rate on continuing operations was 64.8% and (14.0%), respectively. For the nine months ended September 30, 2017 and 2016, the effective tax rate on continuing operations was 70.8% and 43.8%. The primary factors affecting the Company's effective tax rate for the three and nine months ended September 30, 2017, were the method for estimating income taxes at interim periods, the mix of earnings among tax jurisdictions, increases in unrecognized tax benefits, 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.

## 12. Earnings per share (“EPS”)

For the three and nine months ended September 30, 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		Nine Months Ended	
	September 30, 2017	2016	September 30, 2017	2016
Weighted average common shares-basic	18,180,845	18,091,650	18,071,093	18,238,533
Effect of dilutive securities				
Unexercised stock options and stock purchase plan	249,667	194,922	164,716	181,126
Unvested time-based restricted stock awards and units	94,470	95,546	117,320	150,202
Unvested market-based restricted stock units	47,809	—	41,413	—
Weighted average common shares-diluted	18,572,791	18,382,118	18,394,542	18,569,861

There were 503,757 and 571,601 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 September 30, 2017 and 2016, respectively, and 534,288 and 468,296 outstanding options, restricted stock, and performance-based or market-based equity awards not included in the diluted earnings per share computation for the nine months ended September 30, 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 Orthofix International N.V.’s (sometimes referred to as “we,” “us” or “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 third quarter of 2017 include the following:

- ◆ Net sales were \$105.2 million, an increase of 6.9% on a reported basis and 6.0% on a constant currency basis
  - ◆ Increase in net sales for all four of our strategic business units, with net sales for Spine Fixation increasing by 19.3%
- Results of Operations

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
	(%)	(%)	(%)	(%)
Net sales	100.0	100.0	100.0	100.0
Cost of sales	22.5	20.2	21.9	21.4
Gross profit	77.5	79.8	78.1	78.6
Sales and marketing	45.1	42.4	46.3	44.0
General and administrative	17.2	19.6	17.9	18.2
Research and development	6.6	7.0	6.7	7.1
Charges related to U.S. Government resolutions	—	1.4	—	4.8
Operating income	8.6	9.4	7.2	4.5
Net income from continuing operations	3.2	10.5	1.8	2.9

## Net Sales by Strategic Business Unit

The following tables provide net sales by SBU:

	Three Months Ended	Percentage Change
--	--------------------	-------------------



September 30,

(U.S. Dollars, in thousands)	2017	2016	Reported	Constant Currency
BioStim	\$44,427	\$42,956	3.4 %	3.4 %
Biologics	15,218	14,335	6.2 %	6.2 %
Extremity Fixation	25,447	24,314	4.7 %	1.4 %
Spine Fixation	20,155	16,892	19.3 %	19.1 %
Net sales	\$105,247	\$98,497	6.9 %	6.0 %

14

(U.S. Dollars, in thousands)	Nine Months Ended		Percentage		Constant	Currency
	September 30,		Change			
	2017	2016	Reported			
BioStim	\$ 136,140	\$ 128,758	5.7 %	5.7 %		%
Biologics	45,866	42,685	7.5 %	7.5 %		%
Extremity Fixation	74,139	75,840	-2.2 %	-2.0 %		%
Spine Fixation	60,782	53,968	12.6 %	12.5 %		%
Net sales	\$ 316,927	\$ 301,251	5.2 %	5.2 %		%

### BioStim

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.

Three months ended September 30, 2017 compared to 2016

Net sales increased \$1.5 million, or 3.4%

• Increase as we continue to leverage the engagement of our expansive sales force, the positive North American Spine Society (“NASS”) coverage recommendation and the launch of our next generation products

• Partially offset by the impact from recent hurricanes in Florida and southern Texas

Nine months ended September 30, 2017 compared to 2016

Net sales increased \$7.4 million, or 5.7%

• Increase as we continue to leverage the engagement of our expansive sales force, the positive North American Spine Society (“NASS”) coverage recommendation and the launch of our next generation products

• Partially offset by the impact from recent hurricanes in Florida and southern Texas

### Biologics

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.

Three months ended September 30, 2017 compared to 2016

Net sales increased \$0.9 million or 6.2%

• Increase in volume for our Trinity products primarily driven by the addition of new distributors over the past several quarters

Nine months ended September 30, 2017 compared to 2016

Net sales increased \$3.2 million or 7.5%

•

Increase in volume for our Trinity products primarily driven by the addition of new distributors over the past several quarters

Benefit from improving performance from our national distribution partner and the reacquisition of a national hospital contract

Extremity Fixation

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.

15

---

Three months ended September 30, 2017 compared to 2016

Net sales increased \$1.1 million or 4.7%

- Increase driven by growth in the U.S., largely due to the continued adoption of our TL-HEX product line
- Increase partly as a result of changes in foreign currency exchange rates, which resulted in an increase of \$0.8 million

- Partially offset by a decrease related to our Extremity Fixation restructuring, which consists of the divestiture of a non-core business in the United Kingdom (“U.K”) and a reduction in sales in Brazil and Puerto Rico as we convert from a direct sales model to the use of stocking distributors of \$0.9 million

Nine months ended September 30, 2017 compared to 2016

Net sales decreased \$1.7 million or 2.2%

- Decrease of \$2.9 million related to our Extremity Fixation restructuring, which consists of the divestiture of a non-core business in the United Kingdom and a reduction in sales in Brazil and Puerto Rico as we convert from a direct sales model to the use of stocking distributors

- Decrease in year-over-year cash collections for the quarter from international distributors whose revenue is recognized upon cash receipt

- Partially offset by growth in the U.S. and the U.K., largely due to the continued adoption of our TL-HEX product line

Spine Fixation

Spine Fixation specializes in the design, development and marketing of a 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.

Three months ended September 30, 2017 compared to 2016

Net sales increased \$3.3 million or 19.3%

- Increase of 21% in U.S. sales due to the addition of new distributor partners in the last several quarters; the uptake of recent product introductions, including our Polyetheretherketone (“PEEK”) / Titanium Composite (“PTC”) family product lines and Cetra; and improved legacy distributor engagement

- Increase in year-over-year international sales, largely due to an increase in sales in Australia

Nine months ended September 30, 2017 compared to 2016

Net sales increased \$6.8 million or 12.6%

- Increase of 20% in U.S. sales due to the addition of new distributor partners in the last several quarters; the uptake of recent product introductions, including our PTC family product lines and Cetra; and improved legacy distributor engagement

- Despite strong performance in certain locations, such as Australia, year-over-year international sales have decreased 15%, largely due to a decrease in order volumes from international stocking distributors

Gross Profit and Non-GAAP Net Margin

Edgar Filing: ORTHOFIX INTERNATIONAL N V - Form 10-Q

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Gross profit	\$81,530	\$78,617	3.7 %	\$247,452	\$236,718	4.5 %
Sales and marketing	(47,493)	(41,717)	13.8 %	(146,496)	(132,582)	10.5 %
Non-GAAP net margin	\$34,037	\$36,900	-7.8 %	\$100,956	\$104,136	-3.1 %
Gross margin	77.5 %	79.8 %	-2.3 %	78.1 %	78.6 %	-0.5 %
Non-GAAP net margin as a percentage of net sales	32.3 %	37.5 %	-5.2 %	31.9 %	34.6 %	-2.7 %

---

Three months ended September 30, 2017 compared to 2016

Gross profit, sales and marketing expense, and non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense, changed as follows:

• Gross profit increased \$2.9 million, primarily due to the growth in net sales. This increase was partially offset by an increase in mix from our Spine Fixation and Extremity Fixation SBUs, which have lower margins; the impact of our conversion to stocking distributors in Brazil and Puerto Rico, and \$0.6 million in non-recurring expenses relating to our U.S. restructuring

• Sales and marketing expense increased \$5.8 million, primarily due to higher commission expenses in the third quarter of 2017 relating to geographic mix, higher rates from new distributors, and a sales and use tax benefit realized in the third quarter of 2016

• Non-GAAP net margin decreased by \$2.9 million as a result of the changes in gross profit and sales and marketing expense

Nine months ended September 30, 2017 compared to 2016

Gross profit, sales and marketing expense, and non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense, changed as follows:

• Gross profit increased \$10.7 million, primarily due to the growth in net sales and partially offset by an increase in inventory-related charges taken for our Extremity Fixation and Spine Fixation SBUs in 2017; an increase in mix from our Spine Fixation and Extremity Fixation SBUs, which have lower margins; the impact of our conversion to stocking distributors in Brazil and Puerto Rico, and \$0.6 million in non-recurring expenses relating to our U.S. restructuring

• Sales and marketing expense increased \$13.9 million, primarily due higher commission expenses in 2017 relating to geographic mix and higher rates from new distributors

• Non-GAAP net margin decreased by \$3.2 million as a result of the changes in gross profit and sales and marketing expense

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	% Change	2017	2016	% Change
(U.S. Dollars, in thousands)						
BioStim	\$18,285	\$19,996	-8.6 %	\$54,887	\$54,980	-0.2 %
Biologics	6,010	6,821	-11.9 %	18,651	19,642	-5.0 %
Extremity Fixation	7,723	8,834	-12.6 %	20,901	24,170	-13.5 %
Spine Fixation	2,122	1,388	52.9 %	6,825	5,925	15.2 %
Corporate	(103 )	(139 )	-25.9 %	(308 )	(581 )	-47.0 %
Non-GAAP net margin	\$34,037	\$36,900	-7.8 %	\$100,956	\$104,136	-3.1 %

General and Administrative Expense

Edgar Filing: ORTHOFIX INTERNATIONAL N V - Form 10-Q

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	% Change	2017	2016	% Change
General and administrative	\$18,068	\$19,272	-6.2 %	\$56,759	\$54,822	3.5 %
As a percentage of net sales	17.2 %	19.6 %	-2.4 %	17.9 %	18.2 %	-0.3 %

Three months ended September 30, 2017 compared to 2016

General and administrative expense decreased \$1.2 million

• Decrease in share-based compensation expense of \$4.3 million, largely related to performance-based awards which were first deemed probable to vest in the third quarter of 2016

• Reductions in Project Bluecore (a multi-year, company-wide process and systems improvement initiative completed in 2016) expenses of \$0.8 million and core expense reductions

• Partially offset by a favorable commercial litigation settlement received in the prior year of \$3.0 million

• Further offset by increased costs associated with our Extremity Fixation and U.S. restructuring initiatives of \$1.0 million and spending relating to strategic investments of \$0.4 million

17

---

Nine months ended September 30, 2017 compared to 2016

General and administrative expense increased \$1.9 million

• Increase in legal settlements of \$4.8 million, largely as a result of a favorable commercial litigation settlement received in the prior year of \$3.0 million

• Increases in spending of \$3.7 million for strategic investments and \$1.1 million as a result of our Extremity Fixation and U.S. restructuring initiatives

• Partially offset by a decrease in share-based compensation expense of \$3.1 million, largely driven by a net decrease in expense attributable to performance-based and market-based awards

• Further offset by reductions in Project Bluecore expenses of \$3.1 million, as the project was completed in 2016, and core expense reductions through savings in other professional fees of \$1.6 million

Research and Development Expense

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Research and development	\$6,935	\$6,858	1.1 %	\$21,246	\$21,294	-0.2 %
As a percentage of net sales	6.6 %	7.0 %	-0.4 %	6.7 %	7.1 %	-0.4 %

Three months ended September 30, 2017 compared to 2016

Research and development expense increased by less than \$0.1 million compared to the prior year

Nine months ended September 30, 2017 compared to 2016

Research and development expense decreased by less than \$0.1 million compared to the prior year

Charges Related to U.S. Government Resolutions

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Charges related to U.S. Government resolutions	\$—	\$1,499	-100.0 %	\$—	\$14,369	-100.0 %
As a percentage of net sales	0.0%	1.4 %	-1.4 %	0.0%	4.8 %	-4.8 %

Three and Nine months ended September 30, 2017 compared to 2016

Decreases of \$1.5 million and \$14.4 million, respectively, related to charges for settlements with the Division of Enforcement of the SEC in 2016 related to the SEC's investigation of our prior self-reported (1) accounting review and restatements of financial statements and (2) allegations of improper payments in Brazil. For additional information, see Note 12 to the financial statements contained within our Form 10-K for the year ended December 31, 2016.

Non-operating Income and Expense



In the first quarter of 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 September 30,			Nine Months Ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Income tax expense	\$6,150	\$(1,276)	-582.0 %	\$13,998	\$6,703	108.8 %
Effective tax rate	64.8 %	-14.0 %	78.8 %	70.8 %	43.8 %	27.0 %

18

---

Three months ended September 30, 2017 compared to 2016

The increase in the effective tax rate was primarily a result of the following factors:

- Increases in unrecognized tax benefits

- A beneficial change in estimate related to the deductibility of certain compensation expenses that did not recur in 2017

The primary factors affecting our effective tax rate for the third quarter of 2017 are as follows:

- Increases in unrecognized tax benefits

- The mix of earnings among tax jurisdictions

- Current period losses in jurisdictions where we do not currently receive a tax benefit

Nine months ended September 30, 2017 compared to 2016

The increase in the effective tax rate was primarily a result of the following factors:

- Increases in unrecognized tax benefits

- A beneficial change in estimate related to the deductibility of certain compensation expenses that did not recur in 2017

- Partially offset by Charges related to U.S. Government resolutions in 2016, which were non-deductible for tax purposes, that did not recur in 2017

The primary factors affecting our effective tax rate for the nine months ended September 30, 2017 are as follows:

- Increases in unrecognized tax benefits

- 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 September 30, 2017, were \$53.9 million compared to \$39.6 million at December 31, 2016.

(U.S. Dollars, in thousands)	Nine Months Ended		
	September 30,		
	2017	2016	Change
Net cash from operating activities	\$23,494	\$38,396	\$(14,902)
Net cash from investing activities	(12,816)	(17,874)	5,058
Net cash from financing activities	2,598	(37,662)	40,260
Effect of exchange rate changes on cash	1,077	301	776
Net change in cash and cash equivalents	\$14,353	\$(16,839)	\$31,192

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)	Nine Months Ended		
	September 30,		
	2017	2016	Change

Net cash from operating activities	\$23,494	\$38,396	\$(14,902)
Capital expenditures	(13,290)	(14,261)	971
Free cash flow	\$10,204	\$24,135	\$(13,931)

Operating Activities

Cash flows from operating activities decreased \$14.9 million

Decrease in net income of \$1.6 million

19

---

Net increase of \$1.9 million for non-cash gains and losses, largely related to the other-than-temporary impairment on the eNeura debt security in the first quarter of 2017, partially offset by changes in share-based compensation expense and deferred income tax expense

Net decrease of \$15.1 million relating to changes in working capital accounts, primarily attributable to increases in our inventory balance as a result of new product introductions and increases in accounts receivable as a result of the increase in net sales

Our two primary working capital accounts are accounts receivable and inventory. Days sales in receivables were 53 days at September 30, 2017 compared to 49 days at September 30, 2016. Inventory turns were 1.2 times as of September 30, 2017 compared to 1.3 times at September 30, 2016 as a result of increased inventory due to new product introductions, primarily in our Spine Fixation and Extremity Fixation SBUs.

#### 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 self-reported accounting matters leading to our prior restatement of financial statements and our self-reported 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.

#### Investing Activities

Cash flows from investing activities increased \$5.1 million

Increase of \$3.6 million from the purchase of certain inventory and intellectual property assets of \$2.6 million and our additional investment in Bone Biologics, Inc. of \$1.0 million during 2016

Increase of \$1.0 million related to reduced capital expenditures, largely as a result of completing Project Bluecore in 2016

#### Financing Activities

Cash flows from financing activities increased \$40.3 million

Increase of \$55.0 million related to the share repurchase plan, which was completed in 2016

Partially offset by a decrease in net proceeds of \$14.7 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 September 30, 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.

20

---

#### 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.

#### Non-GAAP Net Margin

Non-GAAP net margin is an internal metric that we define as gross profit less sales and marketing expense. Non-GAAP 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 September 30, 2017. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2017.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

22

---



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 third 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: October 30, 2017 By: /s/ BRADLEY R. MASON  
Name: Bradley R. Mason  
Title: President and Chief Executive Officer

Date: October 30, 2017 By: /s/ DOUG RICE  
Name: Doug Rice  
Title: Chief Financial Officer