ORTHOFIX INTERNATIONAL N V
Form 10-Q
October 31, 2016

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, 2016

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	Not applicable
(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, or smaller reporting company. See definition of "large accelerated filer," "accelerated filer," "non-accelerated filer" and "smaller reporting 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

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 28, 2016, 17,826,136 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 c 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2015, to reflect new information, the occurrence of future events or circumstances or otherwise.

Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to: the expected sales of our products, including recently launched products; the continuation of our ongoing share repurchase program; our ongoing settlement discussions with the staff of the Division of Enforcement (the "SEC Enforcement Staff") of the Securities and Exchange Commission (the "SEC") related to investigations that arose out of our prior accounting review and restatements of financial statements and our review of allegations of improper payments involving our Brazil-based subsidiary (which are each further described in Note 11 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein); the geographic concentration of certain accounts receivable in countries or territories that are facing severe fiscal challenges; unanticipated expenditures; changing relationships with customers, suppliers, strategic partners and lenders; changes to and the interpretation of governmental regulations; the resolution of pending litigation matters (including our indemnification obligations with respect to certain product liability claims against our former sports medicine global business unit (as further described in Part I, Item 3, "Legal Proceedings"); our ongoing compliance obligations under a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services (and related terms of probation); risks relating to the protection of intellectual property; changes to the reimbursement policies of third parties; the impact of competitive products; changes to the competitive environment; the acceptance of new products in the market; conditions of the orthopedic and spine industries; credit markets and the global economy; corporate development and market development activities, including acquisitions or divestitures; unexpected costs or operating unit performance related to recent acquisitions; and other risks described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as well as in other current and periodic reports that we file with the SEC in the future.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Balance Sheets

(U.S. Dollars, in thousands, except share data)	September 30, 2016	December 31, 2015
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 46,824	$ 63,663
Trade accounts receivable, less allowance for doubtful accounts of $8,840 and $8,923 at September 30, 2016 and December 31, 2015, respectively	52,893	59,839
Inventories	65,013	57,563
Prepaid expenses and other current assets	20,519	31,187
Total current assets	185,249	212,252
Property, plant and equipment, net	51,861	52,306
Patents and other intangible assets, net	8,020	5,302
Goodwill	53,565	53,565
Deferred income taxes	56,222	57,306
Other long-term assets	21,136	19,491
Total assets	$ 376,053	$ 400,222
Liabilities and shareholders' equity		
Current liabilities:		
Trade accounts payable	$ 14,375	$ 16,391
Other current liabilities	68,900	65,597
Total current liabilities	83,275	81,988
Other long-term liabilities	19,598	27,923
Total liabilities	102,873	109,911
Contingencies (Note 11)		
Shareholders' equity:		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,036,712 and 18,659,696 issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	1,804	1,866
Additional paid-in capital	208,109	232,126
Retained earnings	67,415	62,551
Accumulated other comprehensive loss	(4,148)	(6,232)
Total shareholders' equity	273,180	290,311
Total liabilities and shareholders' equity	$ 376,053	$ 400,222

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

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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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Product sales	$84,997	$87,761	$261,490	$251,461
Marketing service fees	13,500	13,390	39,761	40,406
Net sales	98,497	101,151	301,251	291,867
Cost of sales	19,880	23,865	64,533	65,114
Gross profit	78,617	77,286	236,718	226,753
Operating expenses				
Sales and marketing	41,717	46,129	132,582	133,360
General and administrative	18,581	19,348	53,341	63,423
Research and development	6,858	6,523	21,294	18,819
Restatements and related costs	691	1,147	1,481	9,276
Charges related to U.S. Government resolutions (Note 11)	1,499	—	14,369	—
	69,346	73,147	223,067	224,878
Operating income	9,271	4,139	13,651	1,875
Other income and expense				
Interest income (expense), net	471	(125)	320	(323)
Other (expense) income, net	(634)	(1,736)	1,346	(192)
	(163)	(1,861)	1,666	(515)
Income before income taxes	9,108	2,278	15,317	1,360
Income tax benefit (expense)	1,276	(3,066)	(6,703)	(5,808)
Net income (loss) from continuing operations	10,384	(788)	8,614	(4,448)
Discontinued operations (Note 11)				
Loss from discontinued operations	(1,018)	(804)	(3,580)	(2,315)
Income tax benefit	530	221	1,258	585
Net loss from discontinued operations	(488)	(583)	(2,322)	(1,730)
Net income (loss)	$9,896	$(1,371)	$6,292	$(6,178)
Net income (loss) per common share—basic:				
Net income (loss) from continuing operations	$0.57	$(0.04)	$0.47	$(0.24)
Net loss from discontinued operations	(0.02)	(0.03)	(0.13)	(0.09)
Net income (loss) per common share—basic	$0.55	$(0.07)	$0.34	$(0.33)
Net income (loss) per common share—diluted:				
Net income (loss) from continuing operations	$0.56	$(0.04)	$0.46	$(0.24)
Net loss from discontinued operations	(0.02)	(0.03)	(0.12)	(0.09)
Net income (loss) per common share—diluted	$0.54	$(0.07)	$0.34	$(0.33)
Weighted average number of common shares:				
Basic	18,091,650	18,855,533	18,238,533	18,785,696
Diluted	18,382,118	18,855,533	18,569,861	18,785,696
Other comprehensive income (loss):				
Unrealized (loss) gain on derivative instruments, net of tax	(2)	(706)	74	230

Unrealized gain on debt securities, net of tax	3,008	—	539	—
Foreign currency translation adjustment	820	(365)	1,471	(3,666)
Comprehensive income (loss)	$13,722	$(2,442)	$8,376	$(9,614)

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)	Nine Months Ended September 30, 2016	2015 (As Adjusted)
Cash flows from operating activities:		
Net cash provided by operating activities	$38,396	$26,539
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(12,934)	(20,980)
Capital expenditures for intangible assets	(1,327)	(219)
Purchases of assets and investments	(3,613)	—
Purchase of debt securities	—	(15,250)
Net proceeds from sale of assets	—	4,800
Net cash used in investing activities	(17,874)	(31,649)
Cash flows from financing activities:		
Proceeds from issuance of common shares	19,688	3,106
Tax payments for shares withheld to satisfy withholding obligations	(2,354)	(1,437)
Payment of debt issuance costs	—	(1,723)
Changes in restricted cash	—	34,424
Repurchase and retirement of common shares	(54,996)	—
Net cash (used in) provided by financing activities	(37,662)	34,370
Effect of exchange rate changes on cash	301	(2,381)
Net (decrease) increase in cash and cash equivalents	(16,839)	26,879
Cash and cash equivalents at the beginning of the period	63,663	36,815
Cash and cash equivalents at the end of the period	$46,824	$63,694

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

1. Nature of operations, basis of presentation and recently issued accounting pronouncements

Nature of operations

Orthofix International N.V. (together with its subsidiaries, 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 is comprised of four strategic business units (SBUs): BioStim, Biologics, Extremity Fixation and Spine Fixation.

Basis of presentation

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 Annual Report on Form 10-K for the year ended December 31, 2015 (the "2015 Form 10-K"). Operating results for the three and nine months ended September 30, 2016, are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2016. The balance sheet at December 31, 2015, has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

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 shared-based compensation. Actual results could differ from these estimates. As permitted under U.S. GAAP, interim accounting for certain expenses, including income taxes, is based on full year forecasts.

Change in accounting principle for goodwill

During the quarter ended September 30, 2016, the Company voluntarily changed its annual goodwill testing date from the end of the fourth quarter, December 31, to the beginning of the fourth quarter, October 1. The Company believes this change in the method of applying the accounting principle is preferable, as it will more closely align the annual impairment testing date with the most current information from the budgeting and strategic planning process and will provide management with additional time to complete its annual assessment in advance of our year-end reporting. The change will not delay, accelerate or avoid an impairment charge. This change is not applied retrospectively, as it is impracticable to do so because retrospective application would require application of significant estimates and assumptions with the use of hindsight. Accordingly, the change will be applied prospectively.

Recently adopted accounting standard

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, Improvements to Employee Share-Based Payment Accounting. This ASU simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, accounting for forfeitures, and classification on the statement of cash flows. During the quarter ended September 30, 2016, the Company early adopted this new accounting standard with an effective date of January 1, 2016. Under the new standard, all excess tax benefits and tax deficiencies will be recognized as income tax expense or benefit in the income statement as discrete items in the reporting period in which they occur. The Company has applied guidance related to the classification of excess tax benefits on the statement of cash flows on a retrospective basis. Additionally, the Company has elected to account for forfeitures as they occur and recorded the impact of such change on previously reported periods through a $1.4 cumulative-effect adjustment to retained earnings as of January 1, 2016. Further, the Company has applied the guidance for employee taxes paid to tax authorities when shares are withheld to satisfy the employer's statutory income tax withholding obligation on a retrospective basis. The adoption resulted in a $0.3 million decrease in net cash provided by financing activities and a $0.3 million increase in net cash from operating activities for the nine months ended September 30, 2015. The adoption did not have a material impact on the Company's consolidated statement of operations and comprehensive income (loss) for the three and nine month periods ended September 30, 2016.

Recently issued accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 supersedes the revenue recognition requirements in Revenue Recognition (Topic 605), and 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. As currently amended, the standard is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. The standard is to be applied either retrospectively or as a cumulative effect adjustment as of the adoption date. The Company is currently evaluating the effect that adopting this new accounting guidance will have on the consolidated results of operations, cash flows, and financial position and developing processes and procedures to implement this guidance.

In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory. This ASU requires that an entity should measure inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance will be effective prospectively for interim and annual periods beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the new guidance and does not expect it will have a material impact on its consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. This ASU amends various aspects of the recognition, measurement, presentation, and disclosure for certain financial instruments. The guidance will be effective prospectively for annual periods beginning after December 15, 2017, including interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the new guidance and does not expect it will have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires that a lessee recognize lease assets and lease liabilities for those leases classified as operating leases. The guidance is effective for interim and annual periods beginning after December 15, 2018, and will be applied at the beginning of the earliest period presented using a modified retrospective approach. The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

In October 2016, the FASB issued ASU 2016-16, Intra-Entity Transfers of Assets Other Than Inventory. This ASU reduces the complexity in the accounting standards by allowing the recognition of current and deferred income taxes for an intra-entity asset transfer, other than inventory, when the transfer occurs. The guidance will be effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years with early adoption permitted, and is to be applied using a modified retrospective approach. The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

2. Inventories

The Company’s inventories are valued at the lower of cost or estimated net realizable value, after provision for excess or obsolete items, which is reviewed and updated on a periodic basis by management determined on a first-in, first-out basis. Work-in-process and finished products include the cost of materials, labor and other production costs. Finished products include field inventory which represents immediately saleable finished products that are in the possession of

the Company's independent sales representatives, and consignment inventory which represents immediately saleable finished products located at third party customers, such as distributors and hospitals. Deferred cost of sales result from transactions where the Company has shipped product or performed services for which all revenue recognition criteria have not been met. Once the revenue recognition criteria have been met, both the revenues and associated cost of sales are recognized.

Inventories were as follows:

(U.S. Dollars, in thousands)	September 30, 2016	December 31, 2015
Raw materials	$ 4,809	$ 4,976
Work-in-process	7,838	5,087
Finished products	48,358	42,947
Deferred cost of sales	4,008	4,553
Total inventory	$ 65,013	$ 57,563

3. Long-term debt

On August 31, 2015, the Company, through certain of its subsidiaries entered into a Credit Agreement (the "Credit Agreement") with JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lenders party thereto. The Credit Agreement provides for a

five year $125 million secured revolving credit facility (the "Facility"). As of September 30, 2016, the Company has not made any borrowings under the Credit Agreement.

The Credit Agreement contains financial covenants requiring the Company to maintain, as of the last day of any fiscal quarter, a total leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0 based upon the Company's consolidated adjusted earnings. The Company is in compliance with all required financial covenants as of September 30, 2016. The Credit Agreement also includes events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Facility may be accelerated and/or the lenders' commitments terminated.

The Company had not made any borrowings on its €5.8 million ($6.5 million and $6.3 million) available line of credit in Italy at September 30, 2016 and December 31, 2015, respectively. This unsecured line of credit provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

4. Derivative instruments

In the ordinary course of business, the Company is exposed to the impact of changes in interest rates and foreign currency fluctuations. During 2016 and 2015, the Company made use of a foreign cross-currency swap agreement, which is designated and accounted for as a cash flow hedge, to manage cash flow exposure generated from foreign currency fluctuations.

The tables below disclose the types of derivative instruments the Company owns, the classifications and fair values of these instruments within the balance sheet, and the amount of gain (loss) recognized in other comprehensive income (loss). Any gains or losses reported in accumulated other comprehensive income are reclassified into earnings upon maturity.

(U.S. Dollars, in thousands)	Fair value: favorable (unfavorable)	Balance sheet classification
As of September 30, 2016		
Cross-currency swap	$ 2,247	Prepaid expenses and other current assets
Warrants	$ 321	Other long-term assets
As of December 31, 2015		
Cross-currency swap	$ 2,485	Prepaid expenses and other current assets
Warrants	$ 321	Other long-term assets

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(U.S. Dollars, in thousands)	2016	2015	2016	2015
Cross-currency swap unrealized (loss) gain, net of taxes	$ (2)	$ (706)	$ 74	$ 230

Warrants unrealized loss, net of taxes	$ —	$ —	$ —	$ —

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)	September 30, 2016	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 1,594	$—	$1,594	$—
Treasury securities	487	487	—	—
Certificates of deposit	452	452	—	—
Derivative instruments	2,247	—	2,247	—
Debt securities	14,470	—	—	14,470
Total	$ 19,250	$939	$3,841	$14,470
Liabilities				
Deferred compensation plan	$ (1,488)	$—	$(1,488)	$—
Total	$ (1,488)	$—	$(1,488)	$—

(U.S. Dollars, in thousands)	December 31, 2015	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 1,622	$—	$1,622	$—
Treasury securities	495	495	—	—
Certificates of deposit	337	337	—	—
Derivative instruments	2,485	—	2,485	—
Debt securities	12,658	—	—	12,658
Total	$ 17,597	$832	$4,107	$12,658
Liabilities				
Deferred compensation plan	$ (1,503)	$—	$(1,503)	$—
Total	$ (1,503)	$—	$(1,503)	$—

Debt Securities

On March 4, 2015, the Company entered into an Option Agreement (the "Option Agreement") with eNeura, Inc. ("eNeura"), a privately held medical technology company that is developing devices for the treatment of migraines. The Option Agreement provided the Company with an exclusive option to acquire eNeura (the "Option") during an 18-month period following the grant of the Option, which the Company elected to let expire in September 2016. In consideration for the Option, (i) the Company paid a non-refundable $0.3 million fee to eNeura, and (ii) eNeura issued a Convertible Promissory Note (the "eNeura Note") to the Company. The principal amount of the eNeura Note is $15.0 million and interest accrues at 8.0%. The eNeura Note will mature on March 4, 2019 and interest is due when the note matures, provided that if a change in control of eNeura (generally defined as a third party acquisition of fifty percent or more of eNeura's voting equity or all or substantially all of eNeura's assets) occurs prior to the maturity date, the

eNeura Note will automatically convert into preferred stock of eNeura. The investment is recorded in other long-term assets as an available for sale debt security and interest is recorded in interest income.

The fair value of the debt security is based upon significant unobservable inputs, including the use of a discounted cash flows model, requiring the Company to develop its own assumptions; therefore, the Company has categorized this asset as a Level 3 financial asset. One of the more significant unobservable inputs used in the fair value measurement of the debt security is the discount rate. Holding other inputs constant, changes in the discount rate could result in a significant change in the fair value of the debt security. During the first and second quarters of 2016, the Company revised the estimated fair value of the security which resulted in impairments of $0.8 million and $3.0 million, respectively. During the third quarter of 2016, the Company further revised its estimate based on current financial information and other assumptions, resulting in an increase to the fair value of $4.7 million, which the Company recorded in accumulated other comprehensive loss as an unrealized gain on debt securities. The Company continues to classify the accumulated impairment of $2.5 million as temporary in nature as the Company does not intend to sell the debt security nor does it believe that recoverability of the investment will not occur.

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)	
Balance at December 31, 2015	$12,658
Accrued interest income	969
Unrealized gain on debt securities	843
Balance at September 30, 2016	$14,470

6. 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	Derivatives	Debt Securities	Accumulated Other Comprehensive Loss
Balance at December 31, 2015	$ (4,389)	$ 228	$ (2,071)	$ (6,232)
Unrealized gain on derivative instruments, net of tax of $50	—	74	—	74
Unrealized gain on debt securities, net of tax benefit of $304	—	—	539	539
Foreign currency translation adjustment (1)	1,471	—	—	1,471
Balance at September 30, 2016	$ (2,918)	$ 302	$ (1,532)	$ (4,148)

(1) As unremitted earnings generally remain indefinitely reinvested in the non U.S. dollar denominated foreign subsidiaries, no deferred taxes are recognized on the related foreign currency translation adjustment.

7. Earnings per share

For the three and nine months ended September 30, 2016 and 2015, no adjustments were made to net income (loss) for purposes of calculating basic and diluted net income (loss) available to common shareholders. The following is a reconciliation of the weighted average shares used in the basic and diluted net income (loss) per common share computations.

	Three Months Ended	Nine Months Ended

	September 30,		September 30,	
	2016	2015	2016	2015
Weighted average common shares-basic	18,091,650	18,855,533	18,238,533	18,785,696
Effect of dilutive securities:				
Unexercised stock options and employee stock purchase plan, net of treasury share repurchase	290,468	—	331,328	—
Weighted average common shares-diluted	18,382,118	18,855,533	18,569,861	18,785,696

Options to purchase shares of common stock with exercise prices in excess of the average market price of common shares and performance-based restricted stock awards deemed not probable to vest are not included in the computation of diluted earnings per share. There were 571,601 and 468,286 outstanding awards and options not included in the diluted earnings per share computation for the three and nine months ended September 30, 2016, because their inclusion was antidilutive.

Due to the Company having a net loss from continuing operations position for the three and nine months ended September 30, 2015, there were 1,203,424 and 1,153,763 potentially dilutive shares excluded from the computation, respectively, as their effects were antidilutive.

8. Share-based compensation

All share-based compensation awards are measured at the grant date, based on the estimated fair value of the award, and recognized as expense in the condensed consolidated statements of operations over the requisite service period. The Company recognized $8.1 million and $12.2 million, respectively, of share-based compensation expense for the three and nine months ended September 30, 2016 and $1.9 million and $5.5 million, respectively, for the three and nine months ended September 30, 2015.

On June 30, 2014, the Company granted 99,600 shares of performance-based vesting restricted stock to executive officers and certain employees. Vesting is based on achieving adjusted earnings targets in two consecutive rolling four quarter periods prior to December 31, 2017. As of September 30, 2016, the Company determined these performance-based awards were probable to vest, resulting in the recognition of $2.7 million of expense for the quarter ended September 30, 2016.

Between June 30, 2015 and August 5, 2015, the Company granted 110,660 shares of performance-based vesting restricted stock, coupled with performance stock units ("PSUs"), to executive officers and certain employees. Vesting of the restricted stock is based on achieving adjusted earnings or return on invested capital targets as of and for any of the years ended December 31, 2016, 2017 or 2018. As of September 30, 2016, the Company determined these performance-based awards were probable to vest, resulting in the recognition of $2.4 million of expense for the quarter ended September 30, 2016. The PSUs, which represent the potential to receive additional shares of common stock in an amount up to 50% of the shares of restricted stock granted, are based on adjusted earnings and return on invested capital targets as of and for the year ended December 31, 2018.

On July 1, 2016, the Company granted 96,245 market-based PSUs to executive officers and certain employees. The awards, if performance goals are achieved, will be settled in shares of common stock, with one share of common stock issued per PSU if targets are achieved at a 100% level. Awards may be achieved at a minimum level of 50% and a maximum level of 200%. The performance targets are based the Company's stock achieving certain total shareholder return targets relative to specified index companies during a 3-year performance period beginning on July 1, 2016. As of September 30, 2016, approximately $0.5 million of expense has been recognized for these contingent performance units.

During the three months ended September 30, 2016 and 2015, there were 181,235 and 43,326 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the nine months ended September 30, 2016 and 2015, there were 710,026 and 271,166 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

9. Income taxes

For the third quarter, the effective tax rate on continuing operations was (14.0)%, resulting in a benefit of $1.3 million, as compared to 134.6%, resulting in expense of $3.1 million, for the same period in the prior year. Excluding the impact of discrete tax items, the effective tax rate on continuing operations for the third quarter of 2016 and 2015 was 29.2% and 63.3%, respectively. For the first nine months of 2016, the effective tax rate on continuing operations was 43.8%, or $6.7 million, as compared to 427.1%, or $5.8 million, for the same period in the prior year. Excluding the impact of discrete tax items, the effective tax rate on continuing operations for the first nine months of 2016 and 2015 was 66.5% and 279.2%, respectively.

During the third quarter of 2016, the Company changed its estimate relating to the deductibility of certain compensation expenses. This change in estimate reduced tax expense and increased net income from continuing operations by $2.9 million and increased earnings per share by $0.16 for both the three and nine months ended September 30, 2016.

The primary factors affecting the Company's effective tax rate for the three and nine months ended September 30, 2016, were expense categorized as "Charges related to US Government Resolutions," which represents anticipated settlement payments with substantially no tax benefit, and the change in estimate relating to the deductibility of certain compensation expenses. Other factors affecting the Company's effective tax rate for the three and nine months ended September 30, 2016, and 2015 were the mix of earnings among tax jurisdictions, state taxes, and current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit.

During the third quarter of 2015, the Internal Revenue Service commenced an examination of the Company's federal income tax return for 2012. Further, in October 2016, the Company was notified of an examination of the Company's federal income tax return for 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.

10. Business segment information

The Company has four SBUs, which are comprised of BioStim, Biologics, Extremity Fixation, and Spine Fixation supported by corporate activities. The primary metric used in managing the Company is net margin, which the Company defines as gross profit less sales and marketing expense. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information.

The tables below present net sales by SBU reporting segment. Net sales include product sales and marketing service fees. Marketing service fees, which are recorded on a net basis, are comprised of fees earned for the marketing of Trinity Evolution®, Trinity ELITE® and Versashield™ in the Biologics segment.

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2016	2015	Change
BioStim	$42,956	$41,559	3.4 %
Biologics	14,335	14,639	(2.1)%
Extremity Fixation	24,314	24,694	(1.5)%
Spine Fixation	16,892	20,259	(16.6)%
Total net sales	$98,497	$101,151	(2.6)%

(U.S. Dollars, in thousands)	Nine Months Ended September 30, 2016	2015	Change
BioStim	$128,758	$119,962	7.3 %
Biologics	42,685	43,874	(2.7)%
Extremity Fixation	75,840	72,103	5.2 %
Spine Fixation	53,968	55,928	(3.5)%
Total net sales	$301,251	$291,867	3.2 %

The table below presents net margin by SBU reporting segment for the three and nine months ended September 30, 2016 and 2015:

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2016	2015	Nine Months Ended September 30, 2016	2015
BioStim	$19,996	$16,834	$54,980	$47,634
Biologics	6,821	6,296	19,642	19,525
Extremity Fixation	8,834	6,442	24,170	22,607
Spine Fixation	1,388	1,938	5,925	4,582
Corporate	(139)	(353)	(581)	(955)
Total net margin	36,900	31,157	104,136	93,393
General and administrative	18,581	19,348	53,341	63,423
Research and development	6,858	6,523	21,294	18,819
Restatements and related costs	691	1,147	1,481	9,276
Charges related to U.S. Government resolutions	1,499	–	14,369	–

Operating income	$9,271	$4,139	$13,651	$1,875

11. Contingencies

The Company is party to outstanding legal proceedings, investigations and claims, as previously described in (i) Part I, Item 3, “Legal Proceedings,” of the 2015 Form 10-K and (ii) note 14 to the Company’s audited consolidated financial statements filed with the 2015 Form 10-K. The Company believes that it is unlikely that the outcome of any of the matters that remain pending will have a material adverse effect on it and its subsidiaries as a whole, notwithstanding that the unfavorable resolution of any matter may have a material effect on the Company’s net earnings (if any) in any particular quarter. However, the Company cannot predict with any certainty the final outcome of any of these legal proceedings, investigations (including any settlement discussions with the government seeking to resolve such investigations) or claims, and there can be no assurance that the ultimate resolution of any such matters will not have a material adverse impact on the Company’s consolidated financial position, results of operations, or cash flows.

In addition to the matters described in the paragraphs below and in the 2015 Form 10-K, 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. To the extent losses related to these contingencies are both probable and reasonably estimable, the Company accrues appropriate amounts in the accompanying financial statements and provides disclosures as to the possible range of loss in excess of the amount accrued, if such

range is reasonably estimable. The Company believes losses with respect to these additional matters are individually and collectively immaterial as to a possible loss and range of loss.

Commercial Litigation Settlement

During the third quarter of 2016, the Company entered into an agreement to settle an outstanding commercial litigation matter, whereby the Company will receive a $3.0 million cash payment.

Matters Related to the Audit Committee's Review and the Restatement of Certain of our Consolidated Financial Statements

Audit Committee Review

In July 2013, the Audit Committee of our Board of Directors began conducting an independent review, with the assistance of outside professionals, of certain accounting matters. This review resulted in a restatement of our previously filed consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010 and the fiscal quarter ended March 31, 2013, as well as the restatement of certain financial information for the fiscal years ended December 31, 2009, 2008 and 2007.

In connection with the Company's preparation of its consolidated interim quarterly financial statements for the fiscal quarter ended June 30, 2014, the Company determined that certain entries with respect to the previously filed financial statements contained in the filings containing the restatement were not properly accounted for under U.S. GAAP. As a result, the Company determined in August 2014 to restate its previously filed consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011 and quarterly reporting periods contained within the fiscal years ended December 31, 2013 and 2012, as well as the fiscal quarter ended March 31, 2014.

SEC Investigation

In connection with the initiation of the Audit Committee's independent review, the Company initiated contact with the staff of the Division of Enforcement of the SEC (the "SEC Enforcement Staff") in July 2013 to advise them of these matters. The SEC conducted a formal investigation of these matters, and both the Company and the Audit Committee cooperated fully with the SEC.

The Company is currently engaged in discussions with the SEC Enforcement Staff regarding a possible negotiated resolution of these matters as to the Company. Although such discussions remain ongoing, and any agreement reached between the SEC Enforcement Staff and the Company will be subject to approval by the full Commission, the Company has reached an agreement in principle with the SEC Enforcement Staff that any negotiated resolution will include a civil money penalty of approximately $8.3 million, and the Company previously recorded a charge in this amount during the second quarter of 2016 for this matter. However, no assurance can be given that we will be able to achieve a final, definitive resolution with the SEC to resolve this matter on these or other terms, and the failure to resolve this matter on these or other terms could adversely affect our business and operations.

Deferred Prosecution Agreement and Review of Potentially Improper Payments Involving Brazil Subsidiary

In 2012, the Company entered into definitive agreements with the U.S. Department of Justice (the "DOJ") and the SEC agreeing to settle a self-initiated and self-reported internal investigation of our former Mexican subsidiary, Promeca S.A. de C.V. ("Promeca"), regarding non-compliance by Promeca with the U.S. Foreign Corrupt Practices Act (the "FCPA"). As part of the settlement, the Company entered into a three-year deferred prosecution agreement ("DPA") with the DOJ and a consent to final judgment (the "Consent") with the SEC. Under the DPA, the DOJ agreed not to pursue any criminal charges against the Company in connection with the Promeca matter if the Company complied with the terms of the DPA. The DPA took note of the Company's self-reporting of this matter to the DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by the Company. The DPA and the Consent collectively required, among other things that with respect to anti-bribery compliance matters the Company would continue to cooperate fully with the government in any future matters related to corrupt payments, false books and records or inadequate internal controls. In that regard, the Company represented that it had implemented and would continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws, which includes maintaining a system of internal controls. The Company periodically reported to the government during the terms of the DPA and Consent regarding such remediation and implementation of compliance measures.

In August 2013, during the terms of the DPA and Consent, the Company's internal legal department was notified of certain allegations involving potentially improper payments with respect to its Brazilian subsidiary, Orthofix do Brasil Ltda., and promptly contacted both the DOJ and the SEC Enforcement Staff to voluntarily self-report the allegations. Following the self-report, the Company cooperated fully with the DOJ's investigation of those allegations. On June 15, 2015, the Company and the DOJ agreed to extend the term of the DPA for two months (through September 17, 2015) to permit the DOJ additional time to evaluate the

Company's compliance with the internal controls and compliance undertakings in the DPA and to further investigate the Brazil-related allegations. On September 17, 2015, the DOJ extended the term of the DPA for an additional ten months (through July 17, 2016), stating that the Company's efforts to comply with the internal controls and compliance requirements of the DPA during the first eighteen months of the DPA were insufficient. On July 17, 2016, the DPA expired; on July 29, 2016, the DOJ filed with the court a dismissal of the underlying Promeca-related case; and, on August 1, 2016, the court entered an order granting the DOJ's motion to dismiss such case without prejudice.

The Company also fully cooperated with the SEC's investigation of the allegations in Brazil. The Company has been engaged in discussions with the SEC Enforcement Staff regarding a resolution of the Brazil-related allegations as they relate to the SEC's jurisdiction. Although such discussions remain ongoing, and any agreement reached between the SEC Enforcement Staff and the Company will be subject to approval by the full Commission, the Company has reached an agreement in principle with the SEC Enforcement Staff. The Company recorded a charge of $4.6 million in the second quarter of 2016, and a further charge of approximately $1.5 million in the third quarter of 2016, for this matter. However, no assurance can be given that we will be able to achieve a final, definitive resolution with the SEC on these or other terms, and the failure to resolve this matter on these or other terms could adversely affect our business and operations.

Matters Related to the Company's Former Breg Subsidiary 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") pursuant to a stock purchase agreement (the "Breg SPA"). Under the terms of the Breg SPA, upon closing of the sale, the Company and its subsidiary, Orthofix Holdings, Inc., agreed to indemnify 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." The Company incurred losses for settlements and judgments in connection with these matters during the first nine months of 2016 of $0.8 million as compared to $0.3 million in the first nine months of 2015. In addition, several cases remain 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, alleging the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units or who would not have purchased the units had they known they could be injured. In September 2014, the Company entered into a master settlement agreement resolving all pending pre-close claims. Pursuant to the terms of the settlement agreement, the Company paid approximately $1.3 million, and additional amounts owed under the settlement were paid directly by the Company's insurance providers. These amounts paid by the Company were recorded as an expense in discontinued operations during the fiscal quarter ended June 30, 2014. Remaining cold therapy claims include a putative consumer class of individuals who did not suffer physical harm following use of the devices, and an appeal of an adverse July 2012 California jury verdict and a post-close cold therapy claim pending in California state court. As of September 30, 2016, the Company has accrued $5.7 million for the July 2012 verdict and post-close cold therapy liabilities; however, actual liability could be higher or lower than the amount accrued. The putative class action is at an early stage and the Company currently cannot reasonably estimate the possible loss, or range of loss. On October 28, 2016, the California Court of Appeal issued a ruling in Engler v. Breg, Inc. et al., reversing in part and affirming in part the judgment entered against Breg in 2012. The Company is evaluating the ruling.

Charges incurred as a result of this indemnification are reflected as discontinued operations in our Condensed Consolidated Statements of Operations and Comprehensive Loss.

12. Share repurchase plan

The Company’s Board of Directors authorized a share repurchase plan in the fourth quarter of 2015, authorizing the purchase of up to $75 million of the Company’s common stock through and including September 2017. Under the program, common share repurchases to date have consisted of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Exchange Act, though the Company may also make repurchases through block trades or privately negotiated transactions. Repurchases may be made from cash on hand, cash generated from operations, and/or borrowings under the Company’s secured revolving credit facility. The program does not obligate the Company to acquire any specific number of shares and may be discontinued at any time. During the quarter ended September 30, 2016, the Company repurchased 253,063 shares of common stock for $11.1 million with an average price per share of $43.90 which were all retired upon repurchase. As of September 30, 2016, there was $8.4 million remaining under this share repurchase authorization. From October 1, 2016, to October 28, 2016, the Company made additional repurchases of 211,671 shares for an amount equal to $8.4 million to complete the share repurchase plan.

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

The following discussion and analysis addresses the results of our operations which are based upon the condensed consolidated financial statements included herein, which have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"), for the three and nine months ended September 30, 2016, compared to the three and nine months ended September 30, 2015. These discussions should be read in conjunction with our historical consolidated financial statements and related notes thereto and the other financial information included in this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016.

General

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, the Company has four strategic business units (SBUs), BioStim, Biologics, Extremity Fixation and Spine Fixation, which are described in further detail below under "Business Segments." Orthofix® products are widely distributed via the Company's sales representatives, distributors and its subsidiaries. In addition, Orthofix is collaborating on research and development activities with leading organizations such as the Musculoskeletal Transplant Foundation ("MTF") and the Texas Scottish Rite Hospital for Children.

Our strategy in 2016 has been built upon the following key objectives:

(i) Sales Channel Expansion and Optimization – Our objective for 2016 has been to increase revenue for each of our SBUs at a faster rate than their respective markets by growing and optimizing our sales force while expanding our product portfolio with new and innovative products through both internal development and technology licensing and acquisitions. For our BioStim SBU, we are preparing for the launch our next generation of lumbar and cervical bone growth stimulation products in the early part of 2017. For our Biologics SBU, we plan to introduce in the first quarter of 2017 a novel, disposal delivery system for our Trinity® tissues. This system will be particularly beneficial to physicians for minimally invasive surgeries. In our Extremity Fixation SBU, during the third quarter we launched additional components to augment our TrueLok™ and TL Hex™ products, completed our Galaxy Unyco™ damage control limb fixation portfolio, and released on a limited basis our new hip fracture system in Europe. Lastly, in our Spine Fixation SBU, we just launched our PTC Pillar® SA anterior lumbar stand-alone interbody implant and later in this year and toward the middle of 2017, we plan to launch our Cetra™ anterior cervical plate and our expandable interbody line of products. We expect both of these launches will help fill our two notable gaps in products that have limited our sales efforts in this SBU.

(ii) Operating Margin Improvement – With our infrastructure improvement projects now nearing completion, we plan to focus on continuous improvement initiatives in all areas of the company to become more effective and efficient. We expect the resulting cost savings, coupled with absorption of fixed costs from an expected increase in net sales, to continue to improve our operating margins modestly over the next four quarters.

(iii) Investment in Clinical Research – In order to ensure the long-term success of our Company, we plan on continuing to invest significant resources in clinical research, particularly for our regenerative technologies. In 2016, we have initiated and continue work on a variety of clinical studies supporting both our existing products and to identify new indications for our PEMF technologies, such as for the treatment of rotator cuff injuries and knee osteoarthritis. Additionally, we have continued to evaluate and investigate new pre-clinical and clinical studies for our other businesses and technologies to drive long-term growth. This quarter, we enrolled our first patient in a study evaluating the use of PEMF technology for osteoarthritis of the knee. This study will assess the efficacy and safety of the Company's Physio-Stim® system in reducing inflammation and restoring homeostasis of the extracellular matrix, potentially providing symptomatic relief of OA pain, reducing cartilage breakdown and

stimulating new cartilage formation. If successful, this would be the first disease-modifying treatment for osteoarthritis, which according to Centers for Disease Control and Prevention statistics, will affect nearly 1 in 2 people by the age of 85.

In addition, the North American Spine Society (“NASS”) has issued its first-of-its-kind coverage recommendations for electrical bone growth stimulators. These evidence-based coverage policy recommendations support the use of PEMF devices as an adjunct to spinal fusion surgery. The just-issued NASS coverage policy recommends the use of electrical stimulation for spinal fusion healing in all regions of the spine, including cervical and lumbar regions. Currently, Orthofix is the only company with a bone growth stimulator approved by the U.S. Food and Drug Administration (“FDA”) as a noninvasive, adjunctive treatment option for cervical fusion. We expect that the validation of PEMF electrical stimulation from this leading surgical society will further support our efforts to expand the availability and use of the therapy to the many patients who can benefit from it.

Business Segments

The table below presents net margin, which is a Non-GAAP measure, which the Company defines as gross profit less sales and marketing expense, by SBU reporting segment for the three and nine months ended September 30, 2016 and 2015:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(U.S. Dollars, in thousands)	2016	2015	2016	2015
Gross profit	$78,617	$77,286	$236,718	$226,753
Sales and marketing	(41,717)	(46,129)	(132,582)	(133,360)
Total net margin	$36,900	$31,157	$104,136	$93,393
BioStim	$19,996	$16,834	$54,980	$47,634
Biologics	6,821	6,296	19,642	19,525
Extremity Fixation	8,834	6,442	24,170	22,607
Spine Fixation	1,388	1,938	5,925	4,582
Corporate	(139)	(353)	(581)	(955)
Total net margin	$36,900	$31,157	$104,136	$93,393

BioStim

The BioStim SBU manufactures, distributes, and provides support services of market leading devices that enhance bone fusion. These Class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). These devices utilize pulsed electromagnetic field technology, which is supported by strong basic mechanism of action data in the scientific literature and as well as strong level one randomized controlled clinical trials in the medical literature. Current research and clinical studies are also underway to identify potential new clinical indications. This SBU uses distributors and sales representatives to sell its devices to hospitals, doctors and other healthcare providers, and patients, primarily in the U.S.

Biologics

The Biologics SBU provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This SBU specializes in the marketing of the Company’s regenerative tissue forms. Biologics markets its tissues through a network of distributors, independent sales representatives, and affiliates to supply to hospitals, doctors, and other healthcare providers, primarily in the U.S. Our partnership with the MTF allows us to exclusively market our Trinity Evolution and Trinity ELITE tissue forms for musculoskeletal defects to enhance bony fusion.

Extremity Fixation

The Extremity Fixation SBU offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This SBU specializes in the design, development, and marketing of the Company’s orthopedic products used in fracture repair, adult and pediatric deformity correction and bone

reconstruction procedures, including for the foot and ankle. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates to sell orthopedic products to hospitals, doctors, and other health providers, globally.

Spine Fixation

The Spine Fixation SBU 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 through a network of distributors, sales representatives, and affiliates to sell spine products to hospitals, doctors, and other healthcare providers, globally.

Corporate

Corporate activities are comprised of the operating expenses of Orthofix International N.V. and its holding company subsidiaries, along with activities not necessarily identifiable within the four SBUs.

The following table presents certain items in our condensed consolidated statements of operations as a percentage of total net sales for the periods indicated:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
	(%)	(%)	(%)	(%)
Net sales	100.0	100.0	100.0	100.0
Cost of sales	20.2	23.6	21.4	22.3
Gross profit	79.8	76.4	78.6	77.7
Operating expenses:				
Sales and marketing	42.4	45.6	44.0	45.7
General and administrative	18.9	19.1	17.7	21.7
Research and development	7.0	6.4	7.1	6.4
Restatements and related costs	0.7	1.1	0.5	3.3
Charges related to U.S. Government resolutions	1.4	—	4.8	—
Operating income	9.4	4.2	4.5	0.6
Net income (loss)	10.0	(1.4)	2.1	(2.1)

Three and Nine Months Ended September 30, 2016 Compared to Three and Nine Months Ended September 30, 2015

Net Sales

The tables below present net sales by SBU reporting segment for the three and nine months ended September 30, 2016 and 2015. Constant currency, a Non-GAAP measure presented below, measures revenue using foreign currency rates from the comparable, prior-year period, to present revenue at comparable rates. Constant currency is used by the Company’s management to compare revenues with and without the impact of changes in foreign currencies.

	Three Months Ended September 30,					
					Constant Currency	
(U.S. Dollars, in thousands)	2016	2015	Change		Change	
BioStim	$42,956	$41,559	3.4	%	3.4	%
Biologics	14,335	14,639	(2.1	)%	(2.1	)%
Extremity Fixation	24,314	24,694	(1.5	)%	0.0	%
Spine Fixation	16,892	20,259	(16.6	)%	(16.7	)%
Total net sales	$98,497	$101,151	(2.6	)%	(2.3	)%

	Nine Months Ended September 30,			
(U.S. Dollars, in thousands)	2016	2015	Change	Constant

			Currency Change			
BioStim	$128,758	$119,962	7.3	%	7.3	%
Biologics	42,685	43,874	(2.7	)%	(2.7	)%
Extremity Fixation	75,840	72,103	5.2	%	8.1	%
Spine Fixation	53,968	55,928	(3.5	)%	(3.4	)%
Total net sales	$301,251	$291,867	3.2	%	3.9	%

For the third quarter, net sales decreased $2.7 million, or 2.6%, when compared to the same period of the prior year. Excluding the impact of foreign currency, net sales for the third quarter decreased by approximately $2.3 million, or 2.3%, when compared to the same period in the prior year. For the first nine months of 2016, net sales increased $9.4 million, or 3.2%, when compared to the same period of the prior year. Excluding the impact of foreign currency, net sales for the first nine months increased by approximately $11.5 million, or 3.9%, when compared to the same period in the prior year.

Net Sales by SBU

For the third quarter, net sales in our BioStim SBU increased $1.4 million, or 3.4%, as compared to the same period in the prior year. For the first nine months of 2016, net sales in our BioStim SBU increased $8.8 million, or 7.3%, as compared to the same period in the prior year. The growth was primarily driven by increased order counts from an expanding customer base and our order to cash process improvements that increased the overall percentage that we collect on orders and therefore increased net sales.

For the third quarter, net sales in our Biologics SBU decreased $0.3 million, or 2.1%, as compared to the same period in the prior year. Although volume increased for our Trinity ELITE tissue form in the U.S., this increase was offset by an increasing number of competitors in the stem cell allograft market and an associated reduction in average selling price for our products as compared to the same period in the prior year. For the first nine months of 2016, net sales in our Biologics SBU decreased $1.2 million, or 2.7%, as compared to the same period in the prior year. This decrease was primarily driven by the exclusion from a large national hospital account, the addition of competing product offerings and a low single-digit average selling price decrease.

For the third quarter, net sales in our Extremity Fixation SBU decreased $0.4 million, or 1.5%, as compared to the same period in the prior year, driven by a negative impact from foreign currency translation of $0.4 million. Excluding the impact of foreign currency, net sales for the third quarter were consistent with the same period in the prior year. For the first nine months of 2016, net sales in our Extremity Fixation SBU increased $3.7 million, or 5.2%, as compared to the same period in the prior year, despite a negative impact from foreign currency translation of $2.1 million. Excluding the impact of foreign currency, net sales in the first nine months of 2016 for our Extremity Fixation SBU increased $5.8 million, or 8.1%, primarily driven by growth in the U.S. as a result of the increased adoption of our TL-HEX system and higher international cash collections.

For the third quarter, net sales in our Spine Fixation SBU decreased $3.4 million, or 16.6%, as compared to the same period in the prior year. For the first nine months of 2016, net sales in our Spine Fixation SBU decreased $2.0 million, or 3.5%, as compared to the same period in the prior year. These decreases were primarily due to the timing of international cash collections, the loss of several key surgeon customers in the U.S. and exclusion from a large national hospital account.

Gross Profit

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(U.S. Dollars, in thousands)	2016	2015	2016	2015
Net sales	$98,497	$101,151	$301,251	$291,867

Cost of sales	19,880	23,865	64,533	65,114
Total gross profit	$78,617	$77,286	$236,718	$226,753

For the third quarter, gross profit increased by $1.3 million, or 1.7%, and increased $10.0 million, or 4.4% in the first nine months of 2016, when compared to the same period in the prior year. Gross margin was 79.8% in the third quarter of 2016 compared to 76.4% for the same period of the prior year and was 78.6% in the first nine months of 2016 compared to 77.7% for the same period of the prior year. The increases in gross profit and gross margin were primarily driven by lower fixed costs and an increased sales mix for our BioStim products, which have higher margins, compared to our other products.

Operating Expenses

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2016	2015	Nine Months Ended September 30, 2016	2015
Sales and marketing	$41,717	$46,129	$132,582	$133,360
General and administrative	18,581	19,348	53,341	63,423
Research and development	6,858	6,523	21,294	18,819
Restatements and related costs	691	1,147	1,481	9,276
Charges related to U.S. Government resolutions	1,499	–	14,369	–
Total operating expenses	$69,346	$73,147	$223,067	$224,878

Sales and Marketing Expense

For the third quarter, sales and marketing expense decreased $4.4 million, or 9.6%, when compared to the same period in the prior year. The decrease was primarily due to bad debt expense for Puerto Rico in the third quarter of 2015 and a reduction of certain indirect tax liabilities in the current quarter. As a percentage of net sales, sales and marketing expense was 42.4% and 45.6% in the third quarter of 2016 and 2015, respectively.

For the first nine months of 2016, sales and marketing expense decreased $0.8 million, or 0.6%, when compared to the same period in the prior year. The decrease was primarily due to bad debt expense for Puerto Rico in the prior year and a reduction of certain indirect tax liabilities in the current quarter, partially offset by an increase in commissions. As a percentage of net sales, sales and marketing expense was 44.0% and 45.7% in the first nine months of 2016 and 2015, respectively.

General and Administrative Expense

For the third quarter, general and administrative expense decreased $0.8 million, or 4.0%, when compared to the same period in the prior year. The decrease was primarily driven by a commercial litigation settlement whereby the Company will receive a $3.0 million cash payment, a decrease in other professional fees and consulting costs of $1.9 million, and a decrease due to the moratorium on the medical device tax, partially offset by an increase in share-based compensation expense of $5.8 million, which included $4.8 million in expense associated with the vesting probability of the Company’s 2014 and 2015 performance-based restricted stock grants. As a percentage of net sales, general and administrative expense was 18.9% and 19.1% in the third quarter of 2016 and 2015, respectively.

For the first nine months of 2016, general and administrative expense decreased $10.1 million, or 15.9%, when compared to the same period in the prior year. The decrease was primarily driven by decreases in other professional and consulting fees of $6.7 million, largely associated with the Company’s internal control remediation efforts and project Bluecore in the prior year, commercial litigation settlement whereby the Company will receive a $3.0 million cash payment, legal costs of $1.1 million due to a legal judgment incurred in the prior year, a decrease of $1.0 million due to the moratorium on the medical device tax in 2016, and reductions in controllable expenses. These decreases were partially offset by an increase in compensation related costs, including share-based compensation expense, of $5.0 million. As a percentage of net sales, general and administrative expense was 17.7% and 21.7% in the first nine months of 2016 and 2015, respectively.

Research and Development Expense

For the third quarter, research and development expense increased $0.3 million, or 5.1%, when compared to the same period in the prior year. The increase was primarily driven by increased costs associated with clinical studies of $0.8 million. As a percentage of net sales, research and development expense was 7.0% and 6.4% in the third quarter of 2016 and 2015, respectively.

For the first nine months of 2016, research and development expense increased $2.5 million, or 13.2%, when compared to the same period in the prior year. The increase was primarily driven by a $1.3 million 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, and increased costs associated with clinical studies of $0.9 million. As a percentage of net sales, research and development expense was 7.1% and 6.4% in the first nine months of 2016 and 2015, respectively.

Restatements and Related Costs

The costs incurred in 2016 are primarily continuing legal fees incurred as part of the SEC Investigation, resulting from the Company’s two prior financial restatements, which are expected to continue to decline in future periods. The costs incurred in 2015 were related to the second of these two restatements and legal costs from the resulting SEC investigation and class action complaint.

Charges Related to U.S. Government Resolutions

The Company recorded $1.5 million and $14.4 million for the third quarter and the first nine months of 2016, respectively. These charges relate to our ongoing settlement discussions with the Division of Enforcement of the SEC related to the SEC's investigation of (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments with respect to our Brazil-based subsidiary. For additional information, see Note 11 of the Notes to the Unaudited Condensed Consolidated Financial Statements.

Non-operating Income and Expense

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(U.S. Dollars, in thousands)	2016	2015	2016	2015
Interest income (expense), net	$471	$(125)	$320	$(323)
Other (expense) income, net	(634)	(1,736)	1,346	(192)
Total non-operating (loss) income	$(163)	$(1,861)	$1,666	$(515)

Interest Income (Expense), Net

Interest income, net was $0.5 million in the third quarter compared to interest expense, net of $0.1 million for the same period in the prior year. Interest income, net was $0.3 million for the first nine months of 2016 compared to interest expense, net of $0.3 million for the same period in the prior year.

Other (Expense) Income, Net

Other expense, net was $0.6 million in the third quarter as compared to $1.7 million for the same period in the prior year. Other income, net was $1.3 million for the first nine months of 2016 compared to other expense, net of $0.2 million for the same period in the prior year. The quarter to date and year to date increases were primarily driven by favorable impacts of foreign exchange rates of $1.1 million and $4.8 million when compared to the prior year, respectively, with the year to date increase partially offset by a $3.1 million gain on the sale of the Company's Tempus Cervical Plate product line in 2015.

Income Taxes

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(U.S. Dollars, in thousands)	2016	2015	2016	2015
Income tax benefit (expense) from continuing operations	$1,276	$(3,066)	$(6,703)	$(5,808)
Effective tax rate	(14.0)%	134.6 %	43.8 %	427.1 %

For the third quarter, our effective tax rate on continuing operations was (14.0)%, resulting in a benefit of $1.3 million, as compared to 134.6%, resulting in expense of $3.1 million, for the same period in the prior year. Excluding the impact of discrete tax items, the effective tax rate on continuing operations for the third quarter of 2016 and 2015 was 29.2% and 63.3%, respectively. In the first nine months of 2016, our effective tax rate on continuing operations was 43.8%, or $6.7 million, as compared to 427.1%, or $5.8 million, for the same period in the prior year. Excluding

the impact of discrete tax items, the effective tax rate on continuing operations for the first nine months of 2016 and 2015 was 66.5% and 279.2%, respectively.

The primary factors affecting the Company's effective tax rate for the three and nine months ended September 30, 2016, were expense categorized as "Charges related to US Government Resolutions", which represents anticipated settlement payments with substantially no tax benefit, and a change in estimate relating to the deductibility of certain compensation expenses. Other factors affecting the Company's effective tax rate for the three and nine months ended September 30, 2016, and 2015 were the mix of earnings among tax jurisdictions, state taxes, and current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit.

Discontinued Operations

Net loss from discontinued operations was approximately $0.5 million and $2.3 million for the third quarter and for the first nine months of 2016, respectively, as compared to net loss of $0.6 million and $1.7 million for the same periods in the prior year. The activity in discontinued operations is comprised of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to our former subsidiary, Breg. We previously agreed to indemnify Breg and its purchaser with respect to such matters as part of the original sale agreement entered into in 2012.

Liquidity and Capital Resources

Cash Flow

Cash and cash equivalents at September 30, 2016, was $46.8 million compared to cash and cash equivalents of $63.7 million at December 31, 2015.

	Nine Months Ended September 30,		
(U.S. Dollars, in thousands)	2016	2015	Change
Net cash provided by operating activities	$38,396	$26,539	$11,857
Net cash used in investing activities	(17,874)	(31,649)	13,775
Net cash (used in) provided by financing activities	(37,662)	34,370	(72,032)
Effect of exchange rate changes on cash	301	(2,381)	2,682
Net (decrease) increase in cash and cash equivalents	$(16,839)	$26,879	$(43,718)

Operating Activities

Net cash provided by operating activities increased for the nine months ended September 30, 2016 largely as a result of the increase in net income as compared to the same period in the prior year. Net income increased $12.5 million to net income of $6.3 million for the nine months ended September 30, 2016, as compared to net loss of $6.2 million for the comparable prior year period.

Investing Activities

Net cash used in investing activities decreased for the nine months ended September 30, 2016 due to the purchase of debt securities in connection with the Option Agreement with eNeura of $15.3 million in the first quarter of 2015 and a decrease in capital expenditures of $6.9 million. These decreases were partially offset by proceeds from the sale of assets of $4.8 million in the prior year, the purchase of certain inventory and intellectual property assets of $2.6 million in the second quarter of 2016, and an increase in our investment in Bone Biologics, Inc. of $1.0 million in the first quarter of 2016.

Financing Activities

Net cash from financing activities decreased for the nine months ended September 30, 2016 largely due to the repurchases of the Company’s common stock under the share repurchase plan authorized by the Board of Directors and the removal of the restricted cash requirement associated with the Company’s credit facility in the prior year. During the first nine months of 2016, the Company repurchased approximately 1.3 million shares for $55.0 million. The

removal of the restricted cash requirement associated with the Company's credit facility also resulted in a decrease in cash flows from financing activities of $34.4 million when compared to the prior year. During the nine months ended September 30, 2016 and 2015, the Company also received proceeds of $17.3 million and $1.7 million, respectively, from the issuance of common stock, net of any shares withheld to cover the Company's statutory income tax withholding obligation. Also, in connection with the Company's credit facility, the Company paid $1.7 million in debt issuance costs during the nine months ended September 30, 2015.

Infrastructure Initiative

In 2014, we initiated project Bluecore to improve the reliability and efficiency of our systems, processes and reporting as well as drive down our overhead expenses. In addition to re-implementing our Oracle ERP platform in the U.S. and Italy, this initiative improved supply chain management, simplified finance and accounting procedures and allowed the Company to reduce the use of manual and redundant processes. The Company's re-implementation of its Oracle ERP platform was placed into production in the U.S. and Italy in the second and third quarters of 2016, respectively. For the nine months ended September 30, 2016, the Company spent $6.4 million pursuant to this initiative, $3.3 million of which was capitalized. Over the life of the project, the Company has spent

$26.6 million, of which $18.1 million has been capitalized. We expect to spend an additional $0.8 million over the remainder of the project.

Credit Facilities

There have been no material changes to our debt instruments as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Share Repurchase Plan

In August 2015, the Company's Board of Directors authorized a share repurchase plan, authorizing the purchase of up to $75 million of the Company's common stock through and including September 2017. Under the program, common share repurchases to date have consisted of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Exchange Act, as amended, though the Company may also make repurchases through block trades or privately negotiated transactions. Repurchases may be made from cash on hand, cash generated from operations, and/or borrowings under the Company's secured revolving credit facility. The program does not obligate the Company to acquire any specific number of shares and may be discontinued at any time. As of September 30, 2016, the Company had repurchased a cumulative total of 1,627,001 shares of common stock for $66.6 million under this authorization. From October 1, 2016 to October 28, 2016, the Company made additional repurchases of 211,671 shares for an amount equal to $8.4 million to complete the share repurchase plan.

Other

The Company has been engaged in settlement discussions with the SEC Enforcement Staff regarding a resolution of the SEC's investigation of (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments involving our Brazil-based subsidiary. Accordingly, the Company has accrued, but not paid as of September 30, 2016, a charge of approximately $14.4 million in connection with these matters. The Company may draw on its credit facility to pay amounts due once a final, definitive resolution of these matters is achieved. For additional information, see Note 11 to the Notes to the Unaudited Condensed Consolidated Financial Statements.

For information regarding Contingencies, see Note 11 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

As a multinational company, we are subject to certain market risks, including foreign currency. We consider a variety of practices to manage these market risks. For information regarding the derivative instruments the Company owns to manage these risks, see Note 4 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

Off-balance Sheet Arrangements

As of September 30, 2016, 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 Annual Report on Form 10-K for the year ended December 31, 2015.

Critical Accounting Policies and Estimates

There have been no material changes to our critical accounting policies, as described in our Annual Report on Form 10-K for the year ended December 31, 2015, except as described below.

Goodwill and Other Intangible Assets

During the quarter ended September 30, 2016, the Company voluntarily changed its annual goodwill testing date from the end of the fourth quarter, December 31, to the beginning of the fourth quarter, October 1. The Company believes this change in the method of applying the accounting principle is preferable, as it will more closely align the annual impairment testing date with the most current information from our budgeting and strategic planning process and will provide management with additional time to complete its annual

assessment in advance of our year-end reporting. The change will not delay, accelerate or avoid an impairment charge. This change is not applied retrospectively as it is impracticable to do so because retrospective application would require application of significant estimates and assumptions with the use of hindsight. Accordingly, the change will be applied prospectively.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a multinational company, we are subject to certain market risks including foreign currency, interest rate, and concentration of credit. We consider a variety of practices to manage these market risks. There have been no material changes to our market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains 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 by the Company in the reports that it files or submits under the Exchange Act is 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 the Company's management, including its President and Chief Executive Officer and its 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 the Company's disclosure controls and procedures as of September 30, 2016. Based on this evaluation, the Company's President and Chief Executive Officer and the Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of September 30, 2016.

Changes in Internal Control over Financial Reporting

There were no changes in the Company’s internal control over financial reporting during the quarter ended September 30, 2016 that have materially affected or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings, see Note 11 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 from the risk factors disclosed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2015.

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

Stock Repurchases Made in the Quarter

Under our share repurchase plan, repurchases are being made from time to time in the open market based on market conditions, securities law limitations and other factors. The following table sets forth information with respect to shares of our common stock purchased by the Company during the third quarter of 2016.

Period	Total Number of Shares Purchased	Average price Paid Per Share	Total Number of Shares Purchased under Approved Stock Repurchase Program	Maximum Dollar Value of Shares Yet to be Purchased under Approved Stock Repurchase Program As of End of Applicable Period
July 2016	45,108	$ 45.83	45,108	$17,472,275
August 2016	119,477	$ 43.30	119,477	$12,299,160
September 2016	88,478	$ 43.74	88,478	$8,429,132

Total	253,063	$ 43.90	253,063	$ 8,429,132

Item 3. Defaults Upon Senior Securities

There are no matters to be reported under this heading.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

There are no matters to be reported under this heading.

Item 6. Exhibits

10.1	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.2	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.3	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Doug Rice (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.4	Form of 2016 Employee Performance Stock Unit Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.5	Form of Time-Based Vesting Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.6	Form of Time-Based Vesting Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.7	Form of Time-Based Vesting Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (annual grant) (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.8	Form of Time-Based Vesting Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (initial grant) (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.9	Letter Agreement, dated July 7, 2016, between Jeffrey M. Schumm, Orthofix International N.V. and Orthofix Inc. (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated herein by reference).
10.10	Change in Control and Severance Agreement, dated September 7, 2016, between Orthofix International N.V. and Davide Bianchi (filed as an exhibit to the Company's current report on Form 8-K filed September 9, 2016 and incorporated herein by reference).
10.11	Amended Employment Contract, dated September 7, 2016, between Orthofix International N.V. and Davide Bianchi (filed as an exhibit to the Company's current report on Form 8-K filed September 9, 2016 and incorporated herein by reference).
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 31, 2016 By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer

Date: October 31, 2016 By: /s/ DOUG RICE
Name: Doug Rice
Title: Chief Financial Officer