ORTHOFIX INTERNATIONAL N V
Form 10-Q
November 03, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

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 incorporation or organization)	(I.R.S. Employer 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. x 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). x 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 x
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 x No

As of October 30, 2015, 18,889,815 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, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “intends,” “predicts,” “potential” or “continue” or other comparable terminol 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 Item 1A under the heading Risk Factors, to reflect new information, or the occurrence of future events or circumstances.

The forward-looking statements in this filing do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to: an investigation by the Division of Enforcement of the Securities and Exchange Commission (the “SEC”) and related securities class action litigation arising out of our prior accounting review and restatements of financial statements; our review of allegations of improper payments involving our Brazil-based subsidiary; the geographic concentration of certain of our sales and accounts receivable in countries or territories that are facing severe fiscal challenges; the expected sales of our products, including recently launched products; 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); 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) and a deferred prosecution agreement with the U.S. Department of Justice; 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, 2014, 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, 2015	December 31, 2014
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 63,694	$ 36,815
Restricted cash	—	34,424
Trade accounts receivable, less allowance for doubtful accounts of $9,468 and $7,285 at September 30, 2015 and December 31, 2014, respectively	56,173	61,358
Inventories	57,766	59,846
Deferred income taxes	35,974	37,413
Prepaid expenses and other current assets	31,884	26,552
Total current assets	245,491	256,408
Property, plant and equipment, net	51,467	48,549
Patents and other intangible assets, net	5,368	7,152
Goodwill	53,565	53,565
Deferred income taxes	19,101	18,541
Other long-term assets	27,457	8,970
Total assets	$ 402,449	$ 393,185
Liabilities and shareholders' equity		
Current liabilities:		
Trade accounts payable	$ 17,009	$ 13,223
Other current liabilities	61,570	53,220
Total current liabilities	78,579	66,443
Deferred income taxes	—	229
Other long-term liabilities	26,664	26,886
Total liabilities	105,243	93,558
Contingencies (Note 11)		
Shareholders' equity:		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,882,661 and 18,611,495 issued and outstanding as of September 30, 2015 and December 31, 2014, respectively	1,888	1,861
Additional paid-in capital	239,954	232,788
Retained earnings	59,182	65,360
Accumulated other comprehensive loss	(3,818)	(382)

Total shareholders' equity	297,206	299,627
Total liabilities and shareholders' equity	$ 402,449	$ 393,185

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

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Product sales	$87,761	$88,296	$251,461	$265,175
Marketing service fees	13,390	12,698	40,406	36,818
Net sales	101,151	100,994	291,867	301,993
Cost of sales	23,865	25,268	65,114	77,455
Gross profit	77,286	75,726	226,753	224,538
Operating expenses				
Sales and marketing	46,129	40,998	133,360	124,182
General and administrative	19,348	19,322	63,423	55,396
Research and development	6,523	6,572	18,819	18,818
Restatements and related costs	1,147	2,326	9,276	12,959
	73,147	69,218	224,878	211,355
Operating income	4,139	6,508	1,875	13,183
Other income and expense				
Interest expense, net	(125)	(395)	(323)	(1,355)
Other expense, net	(1,736)	(1,322)	(192)	(1,231)
	(1,861)	(1,717)	(515)	(2,586)
Income before income taxes	2,278	4,791	1,360	10,597
Income tax expense	(3,066)	(4,763)	(5,808)	(9,251)
Net (loss) income from continuing operations	(788)	28	(4,448)	1,346
Discontinued operations				
(Loss) income from discontinued operations	(804)	260	(2,315)	(6,363)
Income tax benefit	221	164	585	2,278
Net (loss) income from discontinued operations	(583)	424	(1,730)	(4,085)
Net (loss) income	$(1,371)	$452	$(6,178)	$(2,739)
Net (loss) income per common share—basic:				
Net (loss) income from continuing operations	$(0.04)	$—	$(0.24)	$0.07
Net (loss) income from discontinued operations	(0.03)	0.02	(0.09)	(0.22)
Net (loss) income per common share—basic:	$(0.07)	$0.02	$(0.33)	$(0.15)
Net (loss) income per common share—diluted:				
Net (loss) income from continuing operations	$(0.04)	$—	$(0.24)	$0.07
Net (loss) income from discontinued operations	(0.03)	0.02	(0.09)	(0.22)
Net (loss) income per common share—diluted:	$(0.07)	$0.02	$(0.33)	$(0.15)
Weighted average number of common shares:				
Basic	18,855,533	18,577,540	18,785,696	18,408,238
Diluted	18,855,533	18,773,386	18,785,696	18,564,522
Other comprehensive loss:				
Unrealized (loss) gain on derivative instruments, net of tax	(706)	112	230	184
Foreign currency translation adjustment	(365)	(3,302)	(3,666)	(2,728)

Comprehensive loss	$(2,442)	$(2,738)	$(9,614)	$(5,283)

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, 2015	2014
Cash flows from operating activities:		
Net cash provided by operating activities	$26,236	$35,966
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(20,980)	(11,324)
Capital expenditures for intangible assets	(219)	(170)
Net proceeds from sale of assets	4,800	—
Purchase of other investments	—	(1,457)
Purchase of debt securities	(15,250)	—
Net proceeds from sale of other investments	—	32
Net cash used in investing activities	(31,649)	(12,919)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	1,669	10,333
Repayment of long term debt, net	—	(20,000)
Payment of debt issuance costs	(1,723)	—
Changes in restricted cash	34,424	(11,023)
Excess income tax benefit on employee stock-based awards	303	202
Net cash provided by (used in) financing activities	34,673	(20,488)
Effect of exchange rate changes on cash	(2,381)	(1,658)
Net increase in cash and cash equivalents	26,879	901
Cash and cash equivalents at the beginning of the period	36,815	28,924
Cash and cash equivalents at the end of the period	$63,694	$29,825

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 issues accounting pronouncements

Nature of operations

Orthofix International N.V. (together with its subsidiaries, the "Company") is a diversified, global medical device company focused on developing and delivering innovative repair and regenerative technologies to the spine and orthopedic markets. The Company is comprised of four reportable segments: BioStim, Biologics, Extremity Fixation and Spine Fixation supported by corporate activities.

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, 2014 (the "2014 Form 10-K"). Operating results for the three and nine months ended September 30, 2015, are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2015. The balance sheet at December 31, 2014, has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the U.S. 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, are based on full year forecasts. For interim financial reporting purposes, income taxes are recorded based upon estimated annual effective income tax rates taking into consideration discrete items occurring during the period.

Recently issued accounting standards

In April 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-08, Reporting Discontinued Operations and Disclosures of Components of an Entity. The ASU amends the definition of a discontinued operation and also provides new disclosure requirements for disposals meeting the definition, and for those that do not meet the definition, of a discontinued operation. Under the new guidance, a discontinued operation may include a component or a group of components of an entity, or a business or nonprofit activity that has been disposed of or is classified as held for sale, and represents a strategic shift that has or will have a major effect on an entity's operations and financial results. The ASU also expands the scope to include the disposals of equity method investments and acquired businesses held for sale. Adopting this guidance did not have a material impact on the consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. 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. The standard was originally to be effective for public entities for annual and interim periods beginning after December 15, 2016. On July 9, 2015, the FASB agreed to defer the effective date by one year to December 15, 2017 for annual reporting periods beginning after that date. The FASB also agreed to permit early adoption of the standard, but not before the original effective date of December 15, 2016. 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.

In April 2015, the FASB issued ASU 2015-03, Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, which was later clarified further in ASU 2015-15, Interest – Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements. The ASU requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts and premiums. Debt issuance costs related to line-of-credit arrangements may continue to be presented as an asset. The guidance is effective retroactively for interim and annual periods beginning after

December 15, 2015, with early adoption permitted. The guidance did not have a material impact on the consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory. This ASU requires that an entity should measure inventory, unless accounted for under the last-in, first-out ("LIFO") or retail inventory methods, 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 to have a material impact on its consolidated financial statements.

2. Inventories

The Company's inventories are primarily stated at standard cost, which approximates actual cost determined on a first-in, first-out basis. Work-in-process and finished products include material, labor and production overhead costs. Finished products include field inventory which represents immediately saleable finished products that are in the possession of the Company's direct 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, 2015	December 31, 2014
Raw materials	$ 3,344	$ 3,879
Work-in-process	5,156	4,830
Finished products	44,691	45,612
Deferred cost of sales	4,575	5,525
Total inventory	$ 57,766	$ 59,846

3. Long-term debt

On August 31, 2015, the Company, through its subsidiaries Orthofix Holdings, Inc. ("Orthofix Holdings") and Victory Medical Limited ("Victory Medical", and collectively with Orthofix Holdings, the "Borrowers"), entered into a Credit Agreement (the "New Credit Agreement") with JPMorgan Chase Bank, N.A. ("JPMorgan"), as Administrative Agent, and certain lenders party thereto. The New Credit Agreement provides for a five year $125 million secured revolving

credit facility (the "Facility") and replaces the Company's prior 2010 credit facility, which expired and matured pursuant to its terms on August 30, 2015 with no amounts outstanding. As of September 30, 2015, the Borrowers have not made any borrowings under the New Credit Agreement.

Borrowings under the New Credit Agreement may be used for, among other things, working capital and other general corporate purposes (including share repurchases, permitted acquisitions and permitted payments of dividends and other distributions) of the Company and certain of its subsidiaries. The Facility is generally available in U.S. Dollars with up to $50 million of the Facility also available to be borrowed in Euros and Pounds Sterling (together with U.S. Dollars, the "Agreed Currencies"). The New Credit Agreement further permits up to $50 million of the Facility to be utilized for the issuance of letters of credit in the Agreed Currencies. The Borrowers have the ability to increase the amount of the Facility by an aggregate amount of up to $50 million (which increase may take the form of one or more increases to the revolving credit commitments and/or the issuance of one or more new Term A loans) upon satisfaction of certain conditions precedent and receipt of additional commitments by one or more existing or new lenders.

Borrowings under the Facility bear interest at a floating rate, which is, at the Borrowers option, either LIBOR plus an applicable margin ranging from 1.75% to 2.5% or a base rate plus an applicable margin ranging from 0.75% to 1.5% (in each case subject to adjustment based on the Company's total leverage ratio). An unused commitment fee ranging from 0.25% to 0.4% (subject to adjustment based on the Company's total leverage ratio) is payable quarterly in arrears based on the daily amount of the undrawn portion of each lender's revolving credit commitment under the Facility. Fees are payable on outstanding letters of credit at a rate equal to the applicable margin for LIBOR loans, plus certain customary fees payable solely to the issuer of the letter of credit.

The Company and certain of its subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Borrowers' obligations under the New Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the New Credit Agreement are secured by a pledge of substantially all of the tangible and intangible personal property of the Borrowers and each of the Guarantors, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their subsidiaries. The New Credit Agreement contains customary affirmative and negative covenants, including limitations on the Company's and its subsidiaries' ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay subordinated indebtedness and enter into affiliate transactions.

In addition, the New Credit Agreement contains financial covenants requiring the Company on a consolidated basis 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. The Company was in compliance with all required financial covenants at September 30, 2015. The New 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.

In conjunction with obtaining the Facility, the Company incurred debt issuance costs of $1.7 million which are being amortized over the life of the Facility. The debt issuance costs are included in other long-term assets, net of accumulated amortization. All debt issuance costs relating to the prior 2010 credit facility have been fully amortized.

The Company had no borrowings and an unused available line of credit of €5.8 million ($6.5 million and $7.0 million) at September 30, 2015 and December 31, 2014, respectively, on its Italian line of credit. 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

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).

(U.S. Dollars, in thousands)	Fair value: favorable	
As of September 30, 2015	(unfavorable)	Balance sheet location
Cross-currency swap	$ 4,633	Other long-term assets
Warrants	$ 311	Other long-term assets
As of December 31, 2014		
Cross-currency swap	$ 2,504	Other long-term assets
Warrants	$ 321	Other long-term assets

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2015	2014	Nine Months Ended September 30, 2015	2014
Cross-currency swap unrealized gain (loss) recorded in other comprehensive income (loss), net of taxes	$ (706)	$ 112	$ 230	$ 184
Warrants unrealized gain recorded in other comprehensive income (loss), net of taxes	$ —	$ —	$ —	$ —

5. Fair value measurements

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

(U.S. Dollars, in thousands)	Balance September 30, 2015	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 1,622	$—	$1,622	$—
Treasury securities	518	518	—	—
Certificates of deposit	594	594	—	—
Derivative securities	4,944	—	4,944	—
Equity securities	1,457	—	1,457	—
Debt securities	15,694	—	—	15,694
Total	$ 24,829	$1,112	$8,023	$15,694
Liabilities				
Deferred compensation plan	$ (1,554)	$—	$(1,554)	$—
Total	$ (1,554)	$—	$(1,554)	$—

(U.S. Dollars, in thousands)	Balance December 31, 2014	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 1,696	$—	$1,696	$ —
Treasury securities	586	586	—	—
Certificates of deposit	1,510	1,510	—	—
Derivative securities	2,825	—	2,825	—
Equity securities	1,457	—	1,457	—
Total	$ 8,074	$2,096	$5,978	$ —
Liabilities				
Deferred compensation plan	$ (1,886)	$—	$(1,886)	$ —
Total	$ (1,886)	$—	$(1,886)	$ —

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 provides the Company with an exclusive option to acquire eNeura (the "Option") during the 18-month period following the grant of the Option. 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 the earlier of (i) March 4, 2019, or (ii) exercise of the Option. The interest is not due until the note matures and will be forgiven if the Company exercises the option. 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 instrument is based upon significant unobservable inputs, 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, 2015, the Company believes the carrying amount of the investment and accrued interest approximates fair value.

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)	2015
Balance at January 1	$—
Additions to debt securities	15,000
Accrued interest income	694
Balance at September 30	$15,694

6. Accumulated other comprehensive loss

Accumulated other comprehensive loss is comprised of foreign currency translation adjustments, the effective portion of the gain (loss) on the Company's cross-currency swap, which is designated and accounted for as a cash flow hedge, and the unrealized gain (loss) on warrants. The components of and changes in accumulated other comprehensive loss were as follows:

(U.S. Dollars, in thousands)	Foreign Currency Translation Adjustments	Change in Fair Value	Accumulated Other Comprehensive Loss
Balance at December 31, 2014	$ (482)	$ 100	$ (382)
Unrealized gain on derivative instruments, net of tax of $130	—	230	230
Foreign currency translation adjustment (1)	(3,666)	—	(3,666)
Balance at September 30, 2015	$ (4,148)	$ 330	$ (3,818)

(1) As the 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, 2015 and 2014, there were no adjustments 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 loss per common share computations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Weighted average common shares-basic	18,855,533	18,577,540	18,785,696	18,408,238
Effect of dilutive securities:				
Unexercised stock options net of treasury share repurchase	—	195,846	—	156,284
Weighted average common shares-diluted	18,855,533	18,773,386	18,785,696	18,564,522

Performance-based restricted stock awards and options to purchase shares of common stock with exercise prices in excess of the average market price of common shares are not included in the computation of diluted earnings per share. There were 998,992 and 942,366 outstanding awards and options not included in the diluted earnings per share computation for the three and nine months ended September 30, 2015, respectively, because their inclusion was antidilutive. There were 1,023,038 and 1,055,422 outstanding awards and options not included in the diluted earnings per share computation for the three and nine months ended September 30, 2014, respectively, because their inclusion was antidilutive.

Due to the Company being in a net loss from continuing operations position for the three and nine months ended September 30, 2015, no adjustment has been made for potentially dilutive shares totaling 204,432 and 211,397 for any common stock equivalents as their effects would be antidilutive for the quarterly and year-to-date periods, respectively.

8. Share-based compensation

All share-based compensation costs are measured at the grant date, based on the estimated fair value of the award, and are recognized as expense in the condensed consolidated statements of operations over the requisite service period. The Company recognized $1.9 million and $5.5 million of share-based compensation expense for the three and nine months ended September 30, 2015, and $1.7 million and $4.1 million for the three and nine months ended September 30, 2014.

On June 30, 2014, the Company granted 99,600 performance-based restricted share awards to officers and certain employees. Vesting is based on achieving earnings targets in two consecutive rolling four quarter periods. As of September 30, 2015, no expense has been recognized for these contingent restricted share awards.

On June 30, 2015, the Company granted 68,750 performance-based restricted share awards to officers and on August 5, 2015, granted an additional 41,910 performance-based restricted share awards to other members of management. Vesting is based on

achieving earnings and return on invested capital targets as of and for the years ended December 31, 2016, 2017 or 2018. As of September 30, 2015, no expense has been recognized for these contingent restricted share awards.

During the three and nine months ended September 30, 2015, there were 43,326 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. During the three and nine months ended September 30, 2014, there were 69,572 and 501,862 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

In the third quarter, our effective tax rate on continuing operations was 134.6%, or $3.1 million, as compared to 99.4%, or $4.8 million, for the same period in the prior year. Excluding the impact of various discrete charges, the effective tax rate on continuing operations for the third quarter of 2015 and 2014 was 63.3% and 74.7%, respectively. In the first nine months of 2015, our effective tax rate on continuing operations was 427.0%, or $5.8 million, as compared to 87.3%, or $9.3 million, for the same period in the prior year. Excluding the impact of various discrete charges, the effective tax rate on continuing operations for the first nine months of 2015 and 2014 was 279.2% and 68.4%, respectively. The Company's effective tax rate for the three and nine month periods ended September 30, 2015 was impacted by recording a valuation allowance on the net deferred tax assets in Puerto Rico in response to recent fiscal and economic difficulties experienced by the Puerto Rico Commonwealth, the Company's mix of earnings among various 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 our federal income tax return for 2012. The State of Massachusetts also commenced an examination of our state income tax returns for 2012 and 2013. The Company cannot reasonably determine if these examinations will have a material impact on our financial statements and cannot predict the timing regarding resolution of those tax examinations.

As of September 30, 2015 and December 31, 2014, the Company's unrecognized tax benefit was $15.5 million and $15.6 million, respectively. The Company had approximately $0.5 million accrued for payment of interest and penalties as of September 30, 2015 and December 31, 2014. It is reasonably possible that the amount of the unrecognized benefit with respect to certain of our unrecognized tax positions will significantly increase or decrease within the next 12 months. These changes may be the result of settlements of ongoing audits, competent authority proceedings or other events. At this time, an estimate of the range of the reasonably possible outcomes cannot be made.

10. Business segment information

The Company has four strategic business units ("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 is defined 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 for continuing operations 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 our Biologics segment.

	Three Months Ended September 30,			
(U.S. Dollars, in thousands)	2015	2014	Reported Increase (Decrease)	Constant Currency Increase (Decrease)
BioStim	$41,559	$38,285	8.6 %	8.6 %
Biologics	14,639	13,856	5.7 %	5.7 %
Extremity Fixation	24,694	27,636	(10.6)%	3.4 %
Spine Fixation	20,259	21,217	(4.5)%	(3.9)%
Total net sales	$101,151	$100,994	0.2 %	4.1 %

	Nine Months Ended September 30,			
(U.S. Dollars, in thousands)	2015	2014	Reported Increase (Decrease)	Constant Currency Increase (Decrease)
BioStim	$119,962	$114,937	4.4 %	4.4 %
Biologics	43,874	40,718	7.8 %	7.8 %
Extremity Fixation	72,103	82,005	(12.1)%	2.1 %
Spine Fixation	55,928	64,333	(13.1)%	(12.6)%
Total net sales	$291,867	$301,993	(3.4)%	0.6 %

The table below presents net margin by SBU reporting segment:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(U.S. Dollars, in thousands)	2015	2014	2015	2014
BioStim	$16,834	$16,442	$47,634	$49,168
Biologics	6,296	6,504	19,525	19,500
Extremity Fixation	6,442	8,361	22,607	21,952
Spine Fixation	1,938	3,958	4,582	11,147
Corporate	(353)	(537)	(955)	(1,411)
Total net margin	31,157	34,728	93,393	100,356
General and administrative	19,348	19,322	63,423	55,396
Research and development	6,523	6,572	18,819	18,818
Restatements and related costs	1,147	2,326	9,276	12,959
Operating income	$4,139	$6,508	$1,875	$13,183

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 2014 Form 10-K and (ii) note 15 to the Company’s audited consolidated financial statements filed with the 2014 Form 10-K. The Company believes that it is unlikely that the outcome of any of these

matters 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.

We record accruals for certain outstanding legal proceedings, investigations or claims when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, we do not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then we disclose a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If we cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed.

In addition to the matters described in the paragraphs below and in the 2014 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.

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 years ended December 31, 2012, 2011 and 2010 and the quarter ended March 31, 2013, as well as the restatement of certain financial information for the years ended December 31, 2009, 2008 and 2007. This restatement, which we completed and filed in March 2014, is referred to herein as the "Original Restatement."

In connection with the Company's preparation of its consolidated interim quarterly financial statements for the 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 Original 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 years ended December 31, 2013, 2012 and 2011 and quarterly reporting periods contained within the years ended December 31, 2013 and 2012, as well as the quarter ended March 31, 2014. This restatement, which we completed in March 2015, is referred to herein as the "Further Restatement."

SEC Investigation

In connection with the initiation of the Audit Committee's independent review, we 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 Audit Committee and the Company, through respective counsel, have been in direct communication with the SEC Enforcement Staff regarding these matters. The SEC is conducting a formal investigation of these matters, and both the Company and the Audit Committee are cooperating fully with the SEC.

In connection with the above-referenced communications, the Company has received requests from the SEC for documents and other information concerning various accounting practices, internal controls and business practices, and other related matters. Such requests cover the years ended December 31, 2011 and 2012, and in some instances, prior periods. It is anticipated that we may receive additional requests from the SEC in the future, including with respect to the Further Restatement.

We have previously provided notice concerning our communications with the SEC to the Office of Inspector General of the U.S. Department of Health and Human Services ("HHS-OIG") pursuant to our corporate integrity agreement with HHS-OIG.

We cannot predict if, when or how this matter will be resolved or what, if any, actions we may be required to take as part of any resolution of these matters. Any action by the SEC, HHS-OIG or other governmental agency could result in civil or criminal sanctions against us and/or certain of our current and former officers, directors and employees. At this stage in the matter, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

Securities Class Action Complaint

On August 14, 2013, a securities class action complaint against the Company, previously styled Tejinder Singh v. Orthofix International N.V., et al., and which is now styled Plumbers & Pipefitters National Pension Fund v. Orthofix International N.V., et al., was filed in the United States District Court for the Southern District of New York arising out of the then anticipated restatement of our prior financial statements and the matters described above. Since the date of original filing, the complaint has been amended.

The lead plaintiff's complaint, as amended, purports to bring claims on behalf of persons who purchased the Company's common stock between March 2, 2010 and July 29, 2013. The complaint asserts that the Company and four of its former executive officers, Alan W. Milinazzo, Robert S. Vaters, Brian McCollum, and Emily V. Buxton (collectively, the "Individual Defendants"), violated Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Securities and Exchange Commission Rule 10b-5 ("Rule 10b-5") by making false or misleading statements in or relating to the Company's financial statements. The complaint further asserts that the Individual Defendants were liable as control persons under Section 20(a) of the Exchange Act for any violation by the Company of Section 10(b) of the Exchange Act or Rule 10b-5. As relief, the complaint requests compensatory damages on behalf of the proposed class and lead plaintiff's attorneys' fees and costs. On March 6, 2015, the court granted the defendants' motion to dismiss as to Mr. Milinazzo and denied it with respect to the Company and the other Individual Defendants.

On October 22, 2015, following negotiations facilitated by an independent mediator, the Company, the remaining Individual Defendants and their insurers reached an agreement in principle with the plaintiff, individually and on behalf of the class it purports to represent, to settle and release all claims with respect to this matter subject to final court approval. Under the terms of the agreement in principle, the Company, through its insurers, would make a payment to the plaintiff, and the class it purports to represent, to resolve all claims related to the matter, including any claims for plaintiff counsel's fees and expenses. The Company has previously incurred and expensed fees and expenses in connection with this matter up to and exceeding its insurance policy deductible; as a result, the

Company expects that the full amount of the settlement payment will be covered by and paid by its insurers. The parties have notified the court of the settlement in principle, and are currently drafting definitive documentation to memorialize all of the terms of the agreement in principle. The parties currently expect that the settlement documentation will be presented to the court for its review in late November 2015 or early December 2015.

The Company has accrued both the amount of the settlement payment under the agreement in principle, and a corresponding insurance receivable from its insurers, with respect to these matters. However, there can be no assurance that the parties will agree on final documentation, or that the terms of the settlement will be approved by the court as proposed by the parties. In the event that the settlement were not finalized and approved on the terms agreed in principle, we cannot reasonably estimate the possible loss, or range of loss, to the Company in connection with this matter.

Deferred Prosecution Agreement and Review of Potential 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 Mexican subsidiary, Promeca S.A. de C.V. ("Promeca"), regarding non-compliance by Promeca with the Foreign Corrupt Practices Act (the "FCPA"). As part of the settlement, we entered into a three-year deferred prosecution agreement ("DPA") with the DOJ and a consent to final judgment (the "Consent") with the SEC. In August 2013, the Company's internal legal department was notified of certain allegations involving potential improper payments with respect to its Brazilian subsidiary, Orthofix do Brasil Ltda. The Company engaged outside counsel to assist in the review of these matters, focusing on compliance with applicable anti-bribery laws, including the FCPA. Consistent with the provisions of these agreements, the Company contacted the DOJ and the SEC in August 2013 to voluntarily self-report the Brazil-related 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. The Company and its counsel remain in contact with both agencies regarding the status of the review and cannot reasonably estimate any possible loss, or range of loss, in connection with the review, including any effects it may have with respect to the DPA and Consent.

Matters Related to the Company's Former Breg Subsidiary and Possible Indemnification Obligations

On May 24, 2012, we 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 has incurred losses for settlements and judgments in connection with these matters during 2015 and 2014

of $0.3 million and $3.8 million, respectively. 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, Breg was currently and had been 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 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, 2015, we have an accrual of $5.7 million for the July 2012 verdict and post-close cold therapy liabilities; however, the 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.

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, 2015, compared to the three and nine months ended September 30, 2014. 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, 2015.

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, TX, the Company has four strategic business units (SBUs) that include 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 clinical organizations such as the Musculoskeletal Transplant Foundation and the Texas Scottish Rite Hospital for Children.

Our strategy in 2015 is built upon the following key objectives:

(i) Sales Channel Optimization – During the third quarter we continued to expand and improve our sales forces in each of our SBUs. We expect by year-end 2015 we will have achieved our aggressive sales channel optimization objective for the year. Once achieved, we will transition into a steady state of moderate expansion and upgrading of our sales force. During our sales channel optimization efforts this year, we have invested in sales and marketing expenses at a higher rate than we would expect to in the long-term, but these investments have been very effective in gaining traction on our top line revenue.

(ii) Investment in Core Technologies – We are investing in our core technologies by focusing on the three following areas:

(a) First, increasing the rate of new product introductions. During the first nine months of 2015 we have launched seven significant new products in our repair businesses. These include TrueLok Hex and the Unyco monocortical fixation screw in our Extremity Fixation business, along with the Centurion posterior cervical system, Janus midline screw, Phoenix MIS Long Construct, LoneStar Cervical interbody, and the relaunched Azure anterior cervical plate in our Spine Fixation SBU.

(b) Second, expanding our preclinical and clinical research to both support the use and reimbursement of our regenerative products as well as finding new indications for our technologies. These efforts are underway and producing important findings for us to build upon. Some of these projects have been slower to develop or enroll than we were expecting so for the first nine months of 2015 we have spent less than we anticipated in these investments, but we do expect modest acceleration in the next several quarters.

(c) Third, finding and executing deals to acquire products and technologies that will fill our portfolio gaps and drive sales. We continue to identify and acquire rights to tuck-in products, which fill gaps in our fixation SBUs. Most recently, we acquired an expandable vertebral body replacement and have an agreement in principle for an anterior cervical plate in our Spine Fixation SBU, both due to release in 2016. In addition, as previously discussed, our option to purchase eNeura extends until September 2016. Since executing the option agreement in the first quarter, eNeura has made progress on product design improvements, a new clinical trial, and initial commercialization efforts in the US. These are critical areas for us to consider in our option exercise decision.

(iii) Improvement of Infrastructure and Control Environment – In 2014 we initiated project "Bluecore," a multi-year, worldwide initiative to improve the reliability and efficiency of our systems, processes, and reporting. In addition to re-implementing our Oracle ERP platform worldwide, project Bluecore includes the execution of

numerous work streams designed to improve supply chain management, the optimization of finance and accounting procedures, and the transition to less manual processes with fewer redundancies throughout the Company. Bluecore remains within budget and we expect to go live in the U.S. on our new ERP platform during the second quarter of 2016. We will then continue the rollout to the rest of our subsidiaries into 2017. Many of the other Bluecore projects have already been or will be completed by the end of 2015. For the nine months ended September 30, 2015, the Company spent $16.9 million pursuant to this initiative, $12.2 million of which was capitalized.

Business Segments

The table below presents net margin, which is defined as gross profit less sales and marketing expense, by SBU reporting segment for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(U.S. Dollars, in thousands)	2015	2014	2015	2014
BioStim	$16,834	$16,442	$47,634	$49,168
Biologics	6,296	6,504	19,525	19,500
Extremity Fixation	6,442	8,361	22,607	21,952
Spine Fixation	1,938	3,958	4,582	11,147
Corporate	(353)	(537)	(955)	(1,411)
Total net margin	$31,157	$34,728	$93,393	$100,356
As a % of net sales	30.8 %	34.4 %	32.0 %	33.2 %

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 Orthofix's patented 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 both distributors and independent sales representatives to sell its devices to hospitals, doctors and other healthcare providers, 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 regeneration 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 Musculoskeletal Transplant Foundation 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, deformity correction and bone reconstruction procedures. 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, including share-based compensation 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 percent of total net sales for the periods indicated:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	(%)	(%)	(%)	(%)
Net sales	100.0	100.0	100.0	100.0
Cost of sales	23.6	25.0	22.3	25.6
Gross profit	76.4	75.0	77.7	74.4
Operating expenses:				
Sales and marketing	45.6	40.6	45.7	41.1
General and administrative	19.1	19.1	21.7	18.3
Research and development	6.4	6.5	6.4	6.2
Restatements and related costs	1.1	2.3	3.3	4.3
Operating income	4.2	6.5	0.6	4.5
Net (loss) income	(1.4)	0.4	(2.1)	(0.9)

Three and Nine Months Ended September 30, 2015 Compared to Three and Nine Months Ended September 30, 2014

Net Sales

The tables below present net sales by SBU reporting segment for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,					
			Reported		Constant Currency	
(U.S. Dollars, in thousands)	2015	2014	Increase (Decrease)		Increase (Decrease)	
BioStim	$41,559	$38,285	8.6	%	8.6	%
Biologics	14,639	13,856	5.7	%	5.7	%
Extremity Fixation	24,694	27,636	(10.6	)%	3.4	%
Spine Fixation	20,259	21,217	(4.5	)%	(3.9	)%
Total net sales	$101,151	$100,994	0.2	%	4.1	%

	Nine Months Ended September 30,			
(U.S. Dollars, in thousands)	2015	2014	Reported	Constant

			Increase (Decrease)		Currency Increase (Decrease)	
BioStim	$119,962	$114,937	4.4	%	4.4	%
Biologics	43,874	40,718	7.8	%	7.8	%
Extremity Fixation	72,103	82,005	(12.1	)%	2.1	%
Spine Fixation	55,928	64,333	(13.1	)%	(12.6	)%
Total net sales	$291,867	$301,993	(3.4	)%	0.6	%

For the third quarter, net sales increased slightly to $101.2 million when compared to net sales of $101.0 million in the same period of the prior year. Excluding the impact of foreign currency, net sales increased by approximately $4.2 million, or 4.1%, when compared to the same period in the prior year. For the first nine months of 2015, net sales decreased $10.1 million, or 3.4%, to $291.9 million as compared to $302.0 million for the same period in the prior year. Excluding the impact of foreign currency, net sales increased by $1.9 million, or 0.6%, during the first nine months of 2015 when compared to the same period in the prior year.

Net Sales by SBU

In the third quarter, net sales in our BioStim SBU increased $3.3 million, or 8.6%, to $41.6 million as compared to $38.3 million for the same period in the prior year. For the first nine months of 2015, net sales in our BioStim SBU increased $5.0 million, or 4.4%, to $120.0 million as compared to $114.9 million for the same period in the prior year. These increases were primarily due to the expansion of the BioStim sales channel.

In the third quarter, net sales in our Biologics SBU increased $0.8 million, or 5.7%, to $14.6 million as compared to $13.9 million for the same period in the prior year. For the first nine months of 2015, net sales in our Biologics SBU increased $3.2 million, or 7.8%, to $43.9 million as compared to $40.7 million for the same period in the prior year. These increases were primarily driven by an expanded sales channel through additional distributors. The increase for the quarter was partially offset by anticipated low single digit pricing pressures.

In the third quarter, net sales in our Extremity Fixation SBU decreased $2.9 million, or 10.6%, to $24.7 million as compared to $27.6 million for the same period in the prior year, primarily due to a $3.9 million decrease from the impact of foreign currency translation. Excluding the impact of foreign currency, during the third quarter, net sales for our Extremity Fixation SBU increased $0.9 million, or 3.4%, primarily driven by growth in the U.S. and increased cash collections. These increases were partially offset by declining sales in Brazil on a constant currency basis. For the first nine months of 2015, net sales in our Extremity Fixation SBU decreased $9.9 million, or 12.1%, to $72.1 million as compared to $82.0 million for the same period in the prior year, primarily due to an $11.6 million decrease from the impact of foreign currency translation. Excluding the impact of foreign currency, during the first nine months of 2015, net sales for our Extremity Fixation SBU increased $1.7 million, or 2.1%, primarily driven by growth in the U.S. and increased international cash collections. These increases were partially offset by declining sales in Brazil on a constant currency basis.

In the third quarter, net sales in our Spine Fixation SBU decreased $1.0 million, or 4.5%, to $20.3 million as compared to $21.2 million for the same period in the prior year. For the first nine months of 2015, net sales in our Spine Fixation SBU decreased $8.4 million, or 13.1%, to $55.9 million as compared to $64.3 million for the same period in the prior year. These decreases for the third quarter and first nine months of 2015 were primarily due to the disruption of the domestic sales channel following our restructuring of and investment in the domestic sales channel to position us for long-term growth and profitability.

Gross Profit

	Three Months Ended September 30,		Nine Months Ended September 30,	
(U.S. Dollars, in thousands)	2015	2014	2015	2014
Net sales	$101,151	$100,994	$291,867	$301,993
Cost of sales	23,865	25,268	65,114	77,455
Total gross profit	$77,286	$75,726	$226,753	$224,538

In the third quarter, gross profit increased $1.6 million, or 2.1%, to $77.3 million as compared to $75.7 million for the same period in the prior year. Gross profit as a percent of net sales was 76.4% in the third quarter compared to 75.0%

for the same period of the prior year. For the first nine months of 2015, gross profit increased $2.2 million, or 1.0%, to $226.8 million as compared to $224.5 million for the same period in the prior year. Gross profit as a percent of net sales was 77.7% in the first nine months of 2015 and 74.4% in the same period in the prior year. These increases for the third quarter and first nine months of 2015 resulted from decreases in costs of sales. The decrease in cost of sales for the third quarter of 2015 as compared to the prior year is primarily due to the increased sales mix of our BioStim and Biologics regenerative solutions relative to our other products. The decrease in cost of sales for the first nine months is due to changes in foreign exchange rates, shrinkage charges incurred in the second quarter of 2014 of $1.9 million as a result of physical counts of approximately 90% of our field inventory as part of the remediation activities that followed our Original Restatement, and a higher mix of sales in our regenerative businesses, BioStim and Biologics.

Operating Expenses

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2015	2014	Nine Months Ended September 30, 2015	2014
Sales and marketing	$46,129	$40,998	$133,360	$124,182
General and administrative	19,348	19,322	63,423	55,396
Research and development	6,523	6,572	18,819	18,818
Restatements and related costs	1,147	2,326	9,276	12,959
Total operating expenses	$73,147	$69,218	$224,878	$211,355

Sales and Marketing Expense

In the third quarter, sales and marketing expense increased $5.1 million, or 12.5%, to $46.1 million, and increased $9.2 million, or 7.4%, to $133.4 million in the first nine months of 2015, when compared to the same periods of the prior year. These increases for the third quarter and first nine months of 2015 were primarily driven by increases to bad debt expense of $3.0 million and $2.6 million for the quarterly and year-to-date periods, of which $2.0 million resulted from an increase in reserves in response to the recent fiscal and economic difficulties experienced by the Puerto Rico Commonwealth, including receiving downgrades in credit ratings. The increase is also attributable to an overall increase in sales and field-based training personnel, as part of the rebuilding and expansion of our sales organization as well as sales commission quota overachievement in certain territories. As a percent of net sales, sales and marketing expense was 45.6% and 40.6% in the third quarter of 2015 and 2014, respectively, and 45.7% and 41.1% in the first nine months of 2015 and 2014, respectively.

General and Administrative Expense

In the third quarter, general and administrative expense, inclusive of amortization of intangible assets, remained flat at $19.3 million and increased $8.0 million, or 14.5%, to $63.4 million in the first nine months of 2015, when compared to the same periods in the prior year. The slight increase in the third quarter and the increase for the first nine months of 2015 were primarily driven by an increase in professional fees and personnel costs within our finance department as part of our internal control remediation efforts; increased stock-based compensation of $0.3 million and $1.5 million for the quarterly and year-to-date periods, respectively; approximately $1.0 million related to a legal judgment recorded in the second quarter of 2015 for the year-to-date period; and decreased spending of $0.2 million and increased spending of $3.2 million associated with the strengthening of our infrastructure as part of Project Bluecore for the quarterly and year-to-date periods, respectively. These increases were partially offset by the impact of changes in foreign exchange rates for the quarterly and year-to-date periods. As a percent of net sales, general and administrative expense was 19.1% in the third quarter of 2015 and 2014, and 21.7% and 18.3% in the first nine months of 2015 and 2014, respectively.

Research and Development Expense

In the third quarter, research and development expense decreased $0.1 million, or 0.7%, to $6.5 million, and remained flat at $18.8 million in the first nine months of 2015, when compared to the same periods in the prior year. As a percent of net sales, research and development expense was 6.4% and 6.5% in the third quarter of 2015 and 2014, respectively, and 6.4% and 6.2% in the first nine months of 2015 and 2014, respectively.

Restatements and Related Costs

In the third quarter, as part of the restatements of our consolidated financial statements, the Company incurred $1.1 million of charges related to these activities as compared to $2.3 million for the same period in the prior year. The costs incurred in the third quarter of 2015 are primarily continuing legal fees incurred as part of the SEC Investigation and Securities Class Action Complaint, resulting from the Original and Further Restatements. The costs incurred in the third quarter of 2014 are related to our Further Restatement filed in March 2015 and our Original Restatement filed in March 2014.

In the first nine months of 2015, as part of our accounting review and restatements of our consolidated financial statements, the Company incurred $9.3 million of charges related to these activities as compared to $13.0 million for the same period in the prior year. This decrease is due to a reduction in outside consultant costs incurred during our Further Restatement filed in March 2015 when compared to our Original Restatement filed in March 2014. Costs incurred in the first nine months of 2015 relate to the restatement, which was completed in the first quarter of 2015, and the resulting ongoing SEC Investigation and Securities Class Action Complaint.

Non-operating Expenses

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2015	2014	Nine Months Ended September 30, 2015	2014
Interest expense, net	$(125)	$(395)	$(323)	$(1,355)
Other expense, net	(1,736)	(1,322)	(192)	(1,231)
Total non-operating expenses	$(1,861)	$(1,717)	$(515)	$(2,586)

Interest Expense, Net

In the third quarter, interest expense, net was $0.1 million as compared to interest expense, net of $0.4 million for the same period in the prior year. For the first nine months of 2015, interest expense, net was $0.3 million as compared to $1.4 million for the same period in the prior year. The decrease in interest expense for the quarter and for the first nine months of 2015 was primarily driven by interest income of $0.3 million and $0.7 million, respectively, related to the eNeura Convertible Promissory Note and the pay down of all outstanding debt under the Revolving Credit Facility in the third quarter of 2014.

Other Expense, Net

In the third quarter, other expense, net was $1.7 million as compared to $1.3 million for the same period in the prior year. Other expense includes the effect of foreign exchange transactions.

In the first nine months of 2015, other expense, net was $0.2 million as compared to $1.2 million for the same period in the prior year. The decrease was primarily due to a $3.1 million gain on the sale of the Company's Tempus™ Cervical Plate product line in 2015, which was offset by the effect of foreign exchange transactions due to the strengthening of the U.S. Dollar against the Euro and the Brazilian Real during the first nine months of 2015 as compared to the same period in the prior year.

Income Taxes

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2015	2014	Nine Months Ended September 30, 2015	2014
Income tax expense from continuing operations	$(3,066)	$(4,763)	$(5,808)	$(9,251)
Effective tax rate	134.6 %	99.4 %	427.0 %	87.3 %

In the third quarter, our effective tax rate on continuing operations was 134.6%, or $3.1 million, as compared to 99.4%, or $4.8 million, for the same period in the prior year. Excluding the impact of various discrete charges, the effective tax rate on continuing operations for the third quarter of 2015 and 2014 was 63.3% and 74.7%, respectively. In the first nine months of 2015, our effective tax rate on continuing operations was 427.0%, or $5.8 million, as

compared to 87.3%, or $9.3 million, for the same period in the prior year. Excluding the impact of various discrete charges, the effective tax rate on continuing operations for the first nine months of 2015 and 2014 was 279.2% and 68.4%, respectively. The Company's effective tax rate for the three and nine month periods ended September 30, 2015 was impacted by recording a valuation allowance on the net deferred tax assets in Puerto Rico in response to the recent fiscal and economic difficulties in that jurisdiction, the Company's mix of earnings among various tax jurisdictions, state taxes, and current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit.

Discontinued Operations

In the third quarter, net loss from discontinued operations was approximately $0.6 million as compared to net income of $0.4 million for the same period in the prior year. In the first nine months of 2015, net loss from discontinued operations was approximately $1.7 million as compared to net loss of $4.1 million for the same period 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 agreed to indemnify Breg and its purchaser with respect to such matters.

Liquidity and Capital Resources

Cash Flow

Cash and cash equivalents at September 30, 2015, was $63.7 million. This compares to cash and cash equivalents including restricted cash of $71.2 million at December 31, 2014, of which $34.4 million was subject to certain restrictions under the previous senior secured credit agreement as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

	Nine Months Ended September 30,		Year Over Year
(U.S. Dollars, in thousands)	2015	2014	Change
Net cash provided by operating activities	$26,236	$35,966	$(9,730)
Net cash used in investing activities	(31,649)	(12,919)	(18,730)
Net cash provided by (used in) financing activities	34,673	(20,488)	55,161
Effect of exchange rate changes on cash	(2,381)	(1,658)	(723)
Net increase in cash and cash equivalents	$26,879	$901	$25,978

Operating Activities

Net cash provided by operating activities is comprised of net income, non-cash items (including depreciation and amortization, provision for doubtful accounts, share-based compensation and deferred income taxes) and changes in working capital. Net loss increased $3.4 million to net loss of $6.2 million for the nine months ended September 30, 2015, from net loss of $2.7 million for the comparable period in the prior year. Non-cash items for the nine months ended September 30, 2015 increased $2.8 million to $28.2 million compared to non-cash items of $25.4 million in the same period of 2014. Working capital accounts provided $4.2 million of cash for the nine months ended September 30, 2015, and provided $13.3 million for the nine months ended September 30, 2014, specifically driven by trade accounts receivable, inventories, and trade accounts payable.

Investing Activities

Net cash used in investing activities increased for the nine months ended September 30, 2015 due to the purchase of debt securities in connection with the Option Agreement entered into with eNeura of $15.3 million and an increase in

capital expenditures of $9.7 million, partially offset by proceeds from the sale of assets of $4.8 million.

Financing Activities

Net cash provided by financing activities increased for the nine months ended September 30, 2015, due to the removal of the restricted cash requirement at June 30, 2015, as a result of the Company having no balance outstanding on the secured revolving credit facility and compliance with all required covenants, compared to a restricted cash requirement of $34.4 million as of December 31, 2014. The Company also paid debt issuance costs of $1.7 million as part of the credit facility entered into on August 31, 2015, which is discussed below. During the nine months ended September 30, 2015, and 2014, we also received proceeds of $1.7 million and $10.3 million, respectively, from the issuance of 271,166 shares and 501,862 shares, respectively, of our 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, 2014 the Company also paid down $20.0 million of long-term debt.

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. This project is planned to continue through mid-2017. In addition to re-implementing our Oracle ERP platform company-wide, we expect to improve supply chain management, simplify finance and accounting procedures and move

to less manual processes with fewer redundancies throughout the company. Bluecore and other process improvement initiatives remain on schedule and on budget. For the nine months ended September 30, 2015, the Company spent $16.9 million pursuant to this initiative, $12.2 million of which was capitalized.

Credit Facilities

On August 31, 2015, the Company, through its subsidiaries Orthofix Holdings, Inc. (“Orthofix Holdings”) and Victory Medical Limited (“Victory Medical”, and collectively with Orthofix Holdings, the “Borrowers”), entered into a Credit Agreement (the “New Credit Agreement”) with JPMorgan Chase Bank, N.A. (“JPMorgan”), as Administrative Agent, and certain lenders party thereto. The New Credit Agreement provides for a five year $125 million secured revolving credit facility (the “Facility”) and replaces the Company’s prior 2010 credit facility, which expired and matured pursuant to its terms on August 30, 2015 with no amounts outstanding. As of September 30, 2015, the Borrowers have not made any borrowings under the New Credit Agreement. For additional information regarding the terms of the New Credit Agreement, see Note 3 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

The Company had no borrowings and an unused available line of credit of €5.8 million ($6.5 million and $7.0 million) at September 30, 2015, and December 31, 2014, respectively, on its Italian line of credit. 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.

Puerto Rico Commonwealth

Due to the recent fiscal and economic difficulties experienced by the Puerto Rico Commonwealth, which include amongst other factors, failure to satisfy debt service obligations, the issuing of a Fiscal and Economic Growth Plan, and receiving downgrades in credit ratings, the Company increased its accounts receivable reserve estimate, resulting in additional bad debt expense of $2.0 million during the three months ended September 30, 2015. Reserves may increase in the future if economic conditions in Puerto Rico deteriorate further. The Company also expects revenue to decline in the near-term as we will begin on October 1, 2015, to recognize revenue from future transactions with government customers in Puerto Rico when cash is received.

Share Repurchase Plan

The Company’s Board of Directors has 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 are expected to consist primarily of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Securities Exchange Act of 1934, 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 opreations, and/or borrowings under the Company’s new 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.

Other

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, 2015, 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, 2014.

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, 2014, other than the following, which has been added in connection with the Convertible Promissory Note and Option Agreement entered into with eNeura (see Note 5 of the Notes to the Unaudited Condensed Consolidated Financial Statements for further details):

Fair Value Measurements

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Non-financial assets and liabilities of the Company measured at fair value include any long-lived assets or equity method investments that are impaired in a currently reported period. The authoritative guidance also describes three levels of inputs that may be used to measure fair value:

Level 1 ~~qu~~oted prices in active markets for identical assets and liabilities

Level 2 ~~ob~~servable inputs other than quoted prices in active markets for identical assets and liabilities

Level 3 ~~un~~observable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

The Company's financial instruments include cash equivalents, trade accounts receivable, accounts payable, long-term secured debt, trading securities, common stock warrants, available for sale securities and a cross currency derivative contract. The carrying value of accounts receivable, investments and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company's credit facilities carry a floating rate of interest, and therefore, the carrying value is considered to approximate the fair value. Our fair value measurements is a "critical accounting estimate" because changes in the assumptions used to develop the estimate could materially affect key financial measures, specifically as they relate to financial instruments measured using Level 3 inputs.

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, 2014.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

At the end of the period covered by this report, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. As described below, as of December 31, 2014, management has identified material weaknesses in our internal control over financial reporting, which is an integral component of our disclosure controls and procedures. Our remediation efforts with respect to these weaknesses are continuing, and we have determined that these material weaknesses were continuing as of September 30, 2015. As a result of these ongoing material weaknesses, our President and Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2015.

Material Weaknesses in Internal Control over Financial Reporting

The Company’s management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Exchange Act Rule 13a-15(f)). The Company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the

Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation of reliable financial statements for external purposes in accordance with U.S. GAAP. Because of the inherent limitations in any internal control, no matter how well designed, misstatements may occur and not be prevented or detected. Accordingly, even effective internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation. Further, the evaluation of the effectiveness of internal control over financial reporting was made as of a specific date, and continued effectiveness in future periods is subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies and procedures may decline.

In connection with the preparation and filing of the 2014 Form 10-K, the Company's management, including our President and Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2014 based on the framework set forth in "Internal Control—Integrated Framework (September 1992)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, the Company's management concluded that, because of the material weaknesses described below, the Company's internal control over financial reporting was not effective as of December 31, 2014.

A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with our management's evaluation of our internal control over financial reporting described above, our management has identified the following deficiencies that it believes constituted individually, and in the aggregate, material weaknesses in our internal control over financial reporting as of December 31, 2014:

Revenue recognition practices for sales with distributors. In connection with the preparation of the restatement of financial statements that we filed in March 2014 (the "Original Restatement"), we concluded that we recognized revenue in certain instances in advance of all revenue recognition criteria being met, and that our controls were not effective to reasonably ensure accurate recognition of revenue in accordance with U.S. GAAP for certain distributor sales transactions previously recorded by the Company's domestic and international business units. In general, we did not establish and maintain procedures throughout the Company to reasonably ensure proper communication to, and assessment by, the Company's finance and accounting department of deviations from contractually established terms, which included written or unwritten arrangements made with, or extra-contractual terms provided to, Company distributors at the onset of the sale regarding extended payment terms, product return or exchange rights, and similar concessions agreed to subsequent to the initial sale (which were not memorialized by any formal contractual amendment). Such additional terms were not evaluated, or not evaluated correctly, and were not maintained or reflected in Company customer sales files. In addition, Company personnel were not adequately trained with respect to certain revenue recognition principles applicable under U.S. GAAP that may have led to appropriate consideration of the additional terms entered into outside of the written contractual terms.

Accounts receivable reserves. In connection with the preparation of the restatement of financial statements that we filed in March 2015 (the "Further Restatement"), we expanded our procedures of analyzing collections of accounts receivable to ensure accounts receivable included an appropriate reserve for estimated uncollectible amounts. We concluded the Company had incorrectly considered certain deferred revenue amounts when calculating the estimated reserves. Specifically, the computation of the contractual allowances and bad debt allowances, which serves to adjust accounts receivable to the estimated collectible amount, assumed that some percentage of deferred amounts would be collected, rather than deferring the entire amount. In connection with these additional procedures, we believe the

errors identified indicate that the controls relating to the accounts receivable reserve process and calculations were insufficiently designed to detect a material misstatement.

Inventory reserves. In connection with the preparation of the Original Restatement, we concluded that errors occurred in establishing the Company's inventory reserves due to a design deficiency in our controls over the computation and recording of such reserves. Our method of calculating inventory reserves resulted in the misapplication of U.S. GAAP, which caused us to make adjustments in the restated consolidated financial statements. Specifically, our controls were not designed to detect that increases in our forecasted demand for products, which resulted in reductions in subsequent fiscal years to reserves previously recorded. ASC Topic 330 Inventory (specifically ASC 330-10-35-14) states that a write-down of inventory to the lower-of-cost-or-market value at the close of a fiscal year creates a new cost basis that subsequently should not be marked up based on changes in underlying circumstances, and our controls were not designed to prevent such mark ups due to increases in forecasted demand for products. Additionally, in connection with the preparation of the Further Restatement, we concluded our controls were not adequately designed to ensure that we were accurately

calculating excess inventory reserves based on the consideration of overall demand assumptions and for components of “kit” inventory, which is primarily held by our independent sales representatives. Additionally, our controls were not appropriately designed to ensure that when determining needed inventory reserves, we considered inventory held by third parties under inventory purchase obligations.

Foreign subsidiary oversight. In connection with the preparation of the Original Restatement, we concluded that our oversight of certain foreign subsidiaries was insufficiently designed to detect material misstatements of financial information. Specifically, while these entities were included in oversight activities similar to our other locations, we believe the design of our controls did not adequately address the additional risks associated with certain entities. These additional risks include: sales comprised of higher risk distributor revenues; no specific requirements for statutory audits that may detect inadequacies in the Company’s customer and business records; and a business culture where oral agreements were more common, resulting in contract terms that were less likely to be formally documented.

Manual journal entry control procedures. In connection with the completion of the audit for the year ended December 31, 2013, we determined that our controls over manual journal entries were not operating effectively. Specifically, we determined that some manual journal entries were not supported with sufficient documentation and were not adequately or timely reviewed and approved; nor were controls adequately designed to ensure entries recorded to a subsidiary at the corporate level in consolidation were recorded in the appropriate periods once subsequently recognized on the local subsidiary ledgers.

Some of the material weaknesses described above resulted in material misstatements in our annual and interim consolidated financial statements, which were corrected in the Original Restatement and the Further Restatement, respectively.

Remediation of Material Weaknesses

Our management has worked, and continues to work, to strengthen our disclosure controls and procedures and internal control over financial reporting in connection with the material weaknesses that have been described above. We intend to continue taking measures, including engaging outside professionals, as may be necessary and advisable, to assist us as we continue to address and rectify the foregoing material weaknesses. Since the filing of the Original Restatement, the Company has better aligned its current finance department staff, both domestically and internationally, to enhance the review and oversight of the accounting and finance functions. The Company has also added several key positions in its finance department, including director level roles in corporate accounting, U.S. accounting, and technical accounting. The Company continues to implement the remediation efforts described herein. These remediation efforts are being undertaken under the supervision of the Audit and Finance Committee of our Board of Directors, including a new Chair of the Audit and Finance Committee, who joined our Board of Directors in April 2014 as a newly appointed independent director.

We are committed to maintaining an effective control environment and making changes necessary to enhance effectiveness. This commitment has been, and will continue to be, communicated to and reinforced throughout our organization. As part of this commitment, we are implementing an internal audit program that takes into account the nature of our business and the geographies in which we conduct it. We have also updated our code of conduct, and all our employees are required to annually acknowledge their commitment to adhering to its provisions. We have also informed all new employees and regularly remind all existing employees of the availability of our compliance hotline, through which employees at all levels can anonymously submit information or express concerns regarding accounting, financial reporting and other irregularities they may have become aware of or observed.

We are in the process of implementing and continuing to refine the plan for remediation of the ineffective internal control over financial reporting described above. In addition, we have designed and are implementing the specific

remediation initiatives described below:

Management’s remediation with respect to controls over revenue recognition practices relating to the Company’s distributors:

- We have enhanced our revenue recognition training materials for all sales personnel;
- We have conducted training of sales personnel (including senior-level management) pursuant to our updated revenue recognition training materials;
- We have created and implemented an improved sales certification process to identify any sales with deviations from written sales contracts;
- We have added key personnel within our finance department, which we believe will bring additional revenue recognition expertise to address our more complex revenue transactions to help ensure that our revenue recognition policies are correctly applied; and

- We have improved procedures with respect to the proper communication, approval, documentation and accounting review of deviations from written sales contracts.

Management's remediation with respect to controls over the calculation of the Company's accounts receivable reserves:

- We have enhanced the calculation and review of our accounts receivable reserves, including enhancing our model to incorporate separate consideration of deferred revenue for co-pay when calculating estimated reserves;
- We have enhanced the account reporting structure within our general ledger system to provide increased transparency of deferred revenue versus contractual allowances; and
- We have added key personnel within our finance department, which we believe will bring additional deferred revenue co-pay and accounts receivable reserves expertise.

Management's remediation with respect to controls over the computation and recording of the Company's inventory reserves:

- We have enhanced controls over our model for determining inventory reserves to ensure that, once reserves are established in a fiscal year, subsequent write-ups based on demand are not recognized;
- We have enhanced the calculation and review of our inventory reserve analysis, including enhancing our model to capture demand considerations at the component level rather than the aggregated "kit" level, and increasing the involvement of both finance and operational personnel, which we expect to provide better controls to assess excess and obsolete inventory based on the current inventory on hand in relation to the forecast and related reserves; and
- We have implemented new procedures and controls to determine and verify for each period the amounts of inventory purchase obligations with third parties to assess if such amounts are considered excess amounts warranting reserve.

Management's remediation with respect to controls over foreign subsidiary oversight:

- We have changed our structure so that all of our foreign subsidiaries' accounting functions now report to the VP of International Accounting, who then, along with our domestic subsidiaries' accounting functions, report to the VP, Controller within the corporate accounting function, which enhances the review of, and provides additional corporate-level oversight of, their activities;
- We have established and hired a Director of Controls and Process Improvement position, whose primary duties are the design and implementation of processes and procedures to strengthen internal control over financial reporting;
- We have engaged a professional firm to perform testing and evaluation of the Company's internal controls, and to assist the Company in designing and implementing additional financial reporting controls and financial reporting control enhancements; and
- We have evaluated our accounting systems to determine appropriate enhancements, and a plan is being executed that includes upgrading accounting systems at foreign locations.

Management's remediation with respect to controls over manual journal entries:

- We have implemented a new accounting policy setting forth specific requirements regarding supporting documentation standards and review and approval procedures for manual journal entries, including specifying the types and levels of review to be performed based on specifically defined criteria associated with the nature and magnitude of manual journal entries; and
- We have designed and conducted training for the accounting group regarding manual journal entry preparation, documentation and timely review and approval procedures, along with enhancing procedures over subsequently recording journal entries made at the corporate level into the Company's subsidiary general ledgers to ensure such amounts are recorded within the appropriate periods.

We believe the remediation steps outlined above have improved and will continue to improve the effectiveness of our internal control over financial reporting. As we continue to monitor the effectiveness of our internal control over financial reporting in the areas affected by the material weaknesses described above, we will perform additional procedures prescribed by management, including the use of manual mitigating control procedures, and will employ any additional tools and resources deemed necessary to provide assurance that our financial statements continue to be

fairly stated in all material respects. As our management continues to evaluate and work to improve our disclosure controls and procedures and internal control over financial reporting, we may determine to take additional measures to address these deficiencies or determine to modify certain of the remediation measures described above.

Changes in Internal Control over Financial Reporting

Other than the remediation activities described above, there have not been any changes in our internal control over financial reporting during the third quarter of 2015 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings, see Note 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, 2014.

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

The Company has not made any repurchases of its common stock during the third quarter of 2015.

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	Credit Agreement, dated as of August 31, 2015, among Orthofix Holdings, Inc. and Victory Medical Limited as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company’s current report on Form 8-K filed September 1, 2015 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.
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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.

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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: November 3, 2015 By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer

Date: November 3, 2015 By: /s/ DOUG RICE
Name: Doug Rice
Title: Chief Financial Officer

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