

ORTHOFIX INTERNATIONAL N V
Form 10-Q
August 04, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 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
(State or other jurisdiction of
incorporation or organization)

Not applicable
(I.R.S. Employer
Identification No.)

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

7 Abraham de Veerstraat

Curaçao Not applicable
(Address of principal executive offices) (Zip Code)

599-9-4658525

(Registrant's telephone number, including area code)

Not applicable

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

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

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

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

Large Accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company

Non-Accelerated filer (Do not check if a smaller reporting company) Smaller Reporting Company
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of July 31, 2015, 18,850,550 shares of common stock were issued and outstanding.

Table of Contents

	Page
PART I <u>FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets as of June 30, 2015, and December 31, 2014</u>	4
<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2015, and 2014</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2015 and 2014</u>	6
<u>Notes to the Unaudited Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	24
Item 4. <u>Controls and Procedures</u>	24
PART II <u>OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	28
Item 1A. <u>Risk Factors</u>	28
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
Item 3. <u>Defaults Upon Senior Securities</u>	28
Item 4. <u>Mine Safety Disclosures</u>	28
Item 5. <u>Other Information</u>	28
Item 6. <u>Exhibits</u>	28
<u>SIGNATURES</u>	29

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 terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to further update any such statement, or the risk factors described in 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 (including the expiration of our current secured revolving credit facility in August 2015); 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)	June 30, 2015	December 31, 2014
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 55,946	\$ 36,815
Restricted cash	—	34,424
Trade accounts receivable, less allowance for doubtful accounts of \$7,153 and \$7,285 at June 30, 2015 and December 31, 2014, respectively	58,356	61,358
Inventories	59,219	59,846
Deferred income taxes	36,970	37,413
Prepaid expenses and other current assets	24,723	26,552
Total current assets	235,214	256,408
Property, plant and equipment, net	49,963	48,549
Patents and other intangible assets, net	5,626	7,152
Goodwill	53,565	53,565
Deferred income taxes	17,910	18,541
Other long-term assets	26,876	8,970
Total assets	\$ 389,154	\$ 393,185
Liabilities and shareholders' equity		
Current liabilities:		
Trade accounts payable	\$ 17,230	\$ 13,223
Other current liabilities	47,678	53,220
Total current liabilities	64,908	66,443
Deferred income taxes	—	229
Other long-term liabilities	26,569	26,886
Total liabilities	91,477	93,558
Contingencies (Note 12)		
Shareholders' equity:		
Common shares \$0.10 par value; 50,000,000 shares authorized; 18,839,335 and 18,611,495 issued and outstanding as of June 30, 2015 and December 31, 2014, respectively	1,884	1,861
Additional paid-in capital	237,987	232,788
Retained earnings	60,553	65,360

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

Accumulated other comprehensive loss	(2,747)	(382)
Total shareholders' equity	297,677	299,627
Total liabilities and shareholders' equity	\$ 389,154	\$ 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 Income (Loss)

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Product sales	\$86,868	\$88,579	\$163,700	\$176,879
Marketing service fees	14,086	12,406	27,016	24,120
Net sales	100,954	100,985	190,716	200,999
Cost of sales	21,910	25,414	41,249	52,187
Gross profit	79,044	75,571	149,467	148,812
Operating expenses				
Sales and marketing	42,946	42,013	87,231	83,184
General and administrative	22,506	18,214	44,075	36,074
Research and development	6,451	6,313	12,296	12,246
Restatements and related costs	2,213	2,327	8,129	10,633
	74,116	68,867	151,731	142,137
Operating income (loss)	4,928	6,704	(2,264)	6,675
Other income and expense				
Interest income (expense), net	74	(492)	(198)	(960)
Other income	853	363	1,544	91
	927	(129)	1,346	(869)
Income before income taxes	5,855	6,575	(918)	5,806
Income tax expense	(1,778)	(3,309)	(2,742)	(4,488)
Net income (loss) from continuing operations	4,077	3,266	(3,660)	1,318
Discontinued operations				
Loss from discontinued operations	(730)	(5,829)	(1,511)	(6,623)
Income tax benefit	225	1,880	364	2,114
Net loss from discontinued operations	(505)	(3,949)	(1,147)	(4,509)
Net income (loss)	\$3,572	\$(683)	\$(4,807)	\$(3,191)
Net income (loss) per common share—basic:				
Net income (loss) from continuing operations	\$0.22	\$0.18	\$(0.20)	\$0.07
Net loss from discontinued operations	(0.03)	(0.22)	(0.06)	(0.24)
Net income (loss) per common share—basic:	\$0.19	\$(0.04)	\$(0.26)	\$(0.17)
Net income (loss) per common share—diluted:				
Net income (loss) from continuing operations	\$0.21	\$0.18	\$(0.20)	\$0.07
Net loss from discontinued operations	(0.02)	(0.22)	(0.06)	(0.24)
Net income (loss) per common share—diluted:	\$0.19	\$(0.04)	\$(0.26)	\$(0.17)
Weighted average number of common shares:				
Basic	18,769,415	18,445,348	18,750,804	18,322,185
Diluted	18,989,579	18,621,192	18,750,804	18,435,128
Other comprehensive income (loss):				
Unrealized gain (loss) on derivative instruments, net of tax	271	(31)	936	72
Foreign currency translation adjustment	1,559	198	(3,301)	574

Comprehensive income (loss)	\$5,402	\$(516)	\$(7,172)	\$(2,545)
-----------------------------	---------	--------	---	----------	---	----------	---

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)	Six Months Ended	
	June 30, 2015	2014
Cash flows from operating activities:		
Net cash provided by operating activities	\$8,954	\$17,874
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(13,493)	(6,138)
Capital expenditures for intangible assets	(83)	(119)
Net proceeds from sale of assets	4,800	—
Purchase of debt securities	(15,250)	—
Net proceeds from sale of other investments	—	32
Net cash used in investing activities	(24,026)	(6,225)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	1,646	9,520
Changes in restricted cash	34,424	(21,406)
Excess income tax benefit on employee stock-based awards	54	40
Net cash provided by (used in) financing activities	36,124	(11,846)
Effect of exchange rate changes on cash	(1,921)	192
Net increase (decrease) in cash and cash equivalents	19,131	(5)
Cash and cash equivalents at the beginning of the period	36,815	28,924
Cash and cash equivalents at the end of the period	\$55,946	\$28,919

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

ORTHOFIX INTERNATIONAL N.V.

Notes to the Unaudited Condensed Consolidated Financial Statements

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

Nature of operations

Orthofix International N.V. (together with its subsidiaries, the “Company”) is a diversified, global medical device company focused on 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. Operating results for the three and six months ended June 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 contractual allowances, doubtful accounts, inventories, potential goodwill and intangible asset impairment, 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. The 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. 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. The guidance will be effective retroactively for interim and annual periods beginning after December 15, 2015, with early adoption permitted. The Company is evaluating the new guidance and does not expect it to have a material impact on its 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. Cash Flow Statement Classification Error

During the quarter ended June 30, 2015, the Company identified a classification error in its statement of cash flows for the quarter ended March 31, 2015. This error arose because foreign currency exchange rates and cash balances from an incorrect period were used in calculating the line item “Effect of exchange rate changes on cash,” which caused the negative effect of such line item to be overstated by \$2.4 million. This error resulted in an equal and offsetting error to be reflected in the line item “Net cash provided by operating activities,” whereby such line item was overstated by \$2.4 million. The classification error had no effect on the reported net change in cash and cash equivalents, and also had no effect on the consolidated balance sheet, the consolidated statement of operations, or the consolidated statement of stockholders’ equity. Based on our evaluation of relevant quantitative and qualitative factors, we have determined that the classification error is and was immaterial.

This classification error has been corrected in the statement of cash flows for the six months ended June 30, 2015 contained herein. The Company also intends to correct the comparative presentation of the quarter ended March 31, 2015 in its Quarterly Report on Form 10-Q for the quarter ending March 31, 2016.

3. 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) June 30, December
31,

	2015	2014
Raw materials	\$4,200	\$ 3,879
Work-in-process	5,071	4,830
Finished products	44,309	45,612
Deferred cost of sales	5,639	5,525
Total inventory	\$59,219	\$ 59,846

4. Long-term debt

On August 30, 2010, the Company's wholly-owned U.S. holding company, Orthofix Holdings, Inc. ("Orthofix Holdings") entered into a Credit Agreement (the "Credit Agreement") with certain domestic direct and indirect subsidiaries of the Company (the "Guarantors"), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto.

The Credit Agreement initially provided for a five year, \$200 million secured revolving credit facility (the "Revolving Credit Facility"), and a five year, \$100 million secured term loan facility (the "Term Loan Facility," and together with the Revolving Credit Facility, the "Credit Facilities"). On January 15, 2015, at the Company's request, the lenders agreed to reduce the available capacity under the Revolving Credit Facility to \$100 million.

As of June 30, 2015, and December 31, 2014, there was no outstanding principal under either the Term Loan Facility or the Revolving Credit Facility. Any outstanding balance on the Revolving Credit Facility arising in the event that we draw funds in the

future under such facility would be due on August 30, 2015. The Company is currently in negotiations to renew its revolving credit facility and expects to have this completed before the expiration of its current facility.

The amount of net assets of Orthofix Holdings and its subsidiaries that we classify as “restricted” (due to restrictions on the use of such assets pursuant to the terms of the agreement) as of June 30, 2015, and December 31, 2014, is \$187.8 million and \$181.8 million, respectively. In addition, the Credit Agreement contains restrictions on the Company and subsidiaries that are not parties to the Credit Facilities accessing cash held by Orthofix Holdings, Inc. and its subsidiaries (by way of dividend or otherwise). All of the Company’s subsidiaries that are parties to the Credit Agreement generally have access to this cash for operational and debt repayment purposes. As the Company does not carry a balance on the Revolving Credit Facility as of June 30, 2015, and is in compliance with all required covenants, there are no restrictions on cash as of June 30, 2015. The amount of cash of the Company and its subsidiaries that we classify as “restricted” due to these restrictions as of December 31, 2014 was \$34.4 million.

The Company had no borrowings and an unused available line of credit of €5.8 million (\$6.5 million and \$7.0 million) at June 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.

5. 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 June 30, 2015	(unfavorable)	Balance sheet location
Cross-currency swap	\$ 5,807	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

		Three Months Ended	Six Months Ended
		June 30, 2015	June 30, 2014
(U.S. Dollars, in thousands)			
Cross-currency swap unrealized gain (loss)		\$267	\$(31)
		\$936	\$72

recorded in other comprehensive income

(loss), net of taxes

Warrants unrealized gain recorded in other

comprehensive income (loss), net of taxes \$4 \$— \$— \$—

6. Fair value measurements

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

	Balance			
	June 30,			
(U.S. Dollars, in thousands)	2015	Level 1	Level 2	Level 3
Assets				
Collective trust funds	\$1,664	\$—	\$1,664	\$—
Treasury securities	532	532	—	—
Certificates of deposit	1,129	1,129	—	—
Derivative securities	6,118	—	6,118	—
Equity securities	1,457	—	1,457	—
Debt securities	15,390	—	—	15,390
Total	\$26,290	\$1,661	\$9,239	\$15,390
Liabilities				
Deferred compensation plan	\$(1,553)	\$—	\$(1,553)	\$—
Total	\$(1,553)	\$—	\$(1,553)	\$—

	Balance			
	December 31,			
(U.S. Dollars, in thousands)	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. Given the date of the transaction, as of June 30, 2015, the Company believes the carrying amount of the investment and accrued interest approximate 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	390
Balance at June 30	\$ 15,390

7. 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 \$529	—	936	936
Foreign currency translation adjustment (1)	(3,301)	—	(3,301)
Balance at June 30, 2015	\$ (3,783)	\$ 1,036	\$ (2,747)

(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.

8. Earnings per share

For the three and six months ended June 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		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Weighted average common shares-basic	18,769,415	18,445,348	18,750,804	18,322,185
Effect of dilutive securities:				
Unexercised stock options net of treasury share				
repurchase	220,164	175,844	—	112,943
Weighted average common shares-diluted	18,989,579	18,621,192	18,750,804	18,435,128

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 792,149 and 872,039 outstanding awards and options not included in the diluted earnings per share computation for the three and six months ended June 30, 2015, respectively, because their inclusion was antidilutive. There were 945,725 and 1,193,425 outstanding awards and options not included in the diluted earnings per share computation for the three and six months ended June 30, 2014, respectively, because their inclusion was antidilutive.

Due to the Company being in a net loss from continuing operations position for the six months ended June 30, 2015, no adjustment has been made for potentially dilutive shares totaling 209,269 for any common stock equivalents as their effects would be antidilutive.

9. 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 following table shows the detail of share-based compensation by line item in the condensed consolidated statements of operations:

	Three Months Ended	Six Months Ended
	June 30,	June 30,

(U.S. Dollars, in thousands)	2015	2014	2015	2014
Cost of sales	\$112	\$29	\$223	\$58
Sales and marketing	296	429	601	873
General and administrative	1,301	657	2,570	1,299
Research and development	91	71	182	143
Total	\$1,800	\$1,186	\$3,576	\$2,373

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 June 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. 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 June 30, 2015, no expense has been recognized for these contingent restricted share awards.

During the three and six months ended June 30, 2015, there were 81,974 and 227,840 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 six months ended June 30, 2014, there were 168,715 and 432,290 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

10. Income taxes

The Company recognized a \$2.7 million and \$4.5 million provision for income tax on continuing operations which reflects an effective tax rate of (298.7)% and 77.3% on pre-tax income for the six months ended June 30, 2015 and 2014, respectively. Excluding the impact of various discrete charges, the effective tax rate on continuing operations was (256.6)% and 63.2% for the first six months of 2015 and 2014, respectively. The principal factors affecting the Company's June 30, 2015 effective tax rate were the Company's mix of earnings among various tax jurisdictions, state taxes, current period losses in certain jurisdictions for which the Company does not currently provide a tax benefit and variations in the customary relationship between income tax expense and pretax earnings.

As of June 30, 2015 and December 31, 2014, the Company's unrecognized tax benefit was \$15.6 million. The Company had approximately \$0.5 million accrued for payment of interest and penalties as of June 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.

11. 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. Accordingly, our segment information has been prepared based on our four SBU reporting segments.

The table below presents 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 June 30,				Constant	
			Reported		Currency	
(U.S. Dollars, in thousands)	2015	2014	Increase (Decrease)		Increase (Decrease)	
BioStim	\$40,703	\$39,513	3	%	3	%
Biologics	15,274	13,853	10	%	10	%

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

Extremity Fixation	25,594	27,303	(6))%	12	%
Spine Fixation	19,383	20,316	(5))%	(4))%
Total Net Sales	\$100,954	\$100,985	(0))%	5	%

Six Months Ended June 30,

(U.S. Dollars, in thousands)	2015	2014	Reported		Constant	
			Increase (Decrease)	%	Increase (Decrease)	%
BioStim	\$78,403	\$76,650	2	%	2	%
Biologics	29,235	26,863	9	%	9	%
Extremity Fixation	47,409	54,369	(13))%	2	%
Spine Fixation	35,669	43,117	(17))%	(17))%
Total Net Sales	\$190,716	\$200,999	(5))%	(1))%

The table below presents net margin by SBU reporting segment:

(U.S. Dollars, in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Net margin:				
BioStim	\$16,787	\$17,706	\$30,800	\$32,726
Biologics	7,285	6,496	13,229	12,997
Extremity Fixation	9,149	6,656	16,165	13,590
Spine Fixation	3,173	3,130	2,644	7,189
Corporate	(296)	(430)	(602)	(874)
Total net margin	36,098	33,558	62,236	65,628
General and administrative	22,506	18,214	44,075	36,074
Research and development	6,451	6,313	12,296	12,246
Restatements and related costs	2,213	2,327	8,129	10,633
Operating income (loss)	\$4,928	\$6,704	\$(2,264)	\$6,675

12. 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 Company’s Annual Report on Form 10-K for the year ended December 31, 2014 (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 each 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.

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 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. This

matter remains at an early stage and, as of the date of this Form 10-Q, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

Review of Potential Improper Payments Involving Brazil Subsidiary

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. The Company engaged outside counsel to assist in the review of these matters, focusing on compliance with applicable anti-bribery laws, including the Foreign Corrupt Practices Act (the "FCPA"). This review remains ongoing. The FCPA and related provisions of law provide for potential criminal and civil sanctions in connection with anti-bribery violations, including criminal fines, civil penalties, disgorgement of past profits and other kinds of remedies. The Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with this review.

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 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. 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, and the Company and its counsel remain in contact with both agencies regarding the status of the review. 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 and investigate the Brazil-related allegations. The DOJ has informed the Company and the court that it intends to complete its evaluation and further investigation in August 2015, and that it will notify the Company and the court of its proposed course of action shortly thereafter. In the event that the DOJ and the SEC find that the matters related to the Company's Brazilian subsidiary conflict with the Company's obligations under the terms of these agreements, the Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with that review, including any effects it may have with respect to these agreements (including any potential future amendments thereto).

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 not yet reached any settlement or judgment in 2015, and incurred losses for settlements and judgments in connection with these matters during 2014 and 2013 of \$3.8 million and \$6.7 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 June 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 six months ended June 30, 2015, compared to the three and six months ended June 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 June 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 that include BioStim, Biologics, Extremity Fixation and Spine Fixation. 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 year to date 2015 results and financial condition include the following items of significance:

Compared to the first six months of 2014, BioStim revenues increased \$1.8 million to \$78.4 million, or 2.3%, Biologics increased \$2.4 million to \$29.2 million, or 8.8%, Extremity Fixation revenues decreased \$7.0 million to \$47.4 million, or 12.8%, and Spine Fixation decreased \$7.4 million to \$35.7 million, or 17.3%.

The increase in gross profit margin from 74.0% in the first six months of 2014 to 78.4% in the first six months of 2015 was primarily due to the effect of foreign exchange rates and shrinkage charges incurred in the second quarter of 2014 as the Company counted approximately 90% of its field inventory as part of the remediation activities that followed our Original Restatement, partially offset by the decrease in sales discussed above.

The increase in operating expenses in the first six months of 2015 compared to the first six months of 2014 was primarily a result of an increase in general and administrative expense as well as sales and marketing expense as the Company strengthened its internal infrastructure and sales force, offset by a decrease in restatement and related costs due to a decrease in external consultant costs.

2015 Outlook

For fiscal year 2015, the Company expects net sales in the range of \$390 million to \$395 million, representing a year over year increase of 0.6% to 1.9% on a constant currency basis and a decline of 3.1% to 1.8% on a reported basis.

Business Segments

Our segment information is prepared on the same basis that management reviews the financial information for operational decision making purposes. We manage our business by our four strategic business units ("SBUs"), which are comprised of BioStim, Biologics, Extremity Fixation, and Spine Fixation supported by corporate activities. These SBUs represent the segments for which our Chief Executive Officer, who is also our Chief Operating Decision Maker (the "CODM") reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information has been prepared based on our four SBU reporting segments. The primary metric used in managing the Company is net margin, which is defined as gross profit less sales and marketing expense from continuing operations. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. These four segments are discussed

below.

16

The table below presents net margin by SBU reporting segment:

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Net Margin				
BioStim	\$16,787	\$17,706	\$30,800	\$32,726
Biologics	7,285	6,496	13,229	12,997
Extremity Fixation	9,149	6,656	16,165	13,590
Spine Fixation	3,173	3,130	2,644	7,189
Corporate	(296)	(430)	(602)	(874)
Total net margin	\$36,098	\$33,558	\$62,236	\$65,628
As a % of net sales	35.8 %	33.2 %	32.6 %	32.7 %

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 ("PEMF") 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 ("MTF") allows us to exclusively market our Trinity Evolution® and Trinity ELITE® tissue forms for musculoskeletal defects to enhance bony fusion.

Extremity Fixation

The Extremity Fixation SBU offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This SBU specializes in the design, development, and marketing of the Company's orthopedic products used in fracture repair, deformity correction and bone reconstruction procedures. Extremity Fixation distributes its products through a network of distributors, independent sales representatives and affiliates. This SBU uses both independent distributors and direct sales representatives 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 and affiliates. This SBU uses distributors and independent sales representatives 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.

SBU Net Sales

The table below presents net sales for the three and six months ended June 30, 2015 and 2014, from continuing operations, by SBU reporting segment:

(U.S. Dollars, in thousands)	Three Months Ended June 30,				Constant	
	2015	2014	Reported		Currency	
			Increase		Increase	
			(Decrease)		(Decrease)	
BioStim	\$40,703	\$39,513	3	%	3	%
Biologics	15,274	13,853	10	%	10	%
Extremity Fixation	25,594	27,303	(6))%	12	%
Spine Fixation	19,383	20,316	(5))%	(4))%
Total Net Sales	\$100,954	\$100,985	(0))%	5	%

(U.S. Dollars, in thousands)	Six Months Ended June 30,				Constant	
	2015	2014	Reported		Currency	
			Increase		Increase	
			(Decrease)		(Decrease)	
BioStim	\$78,403	\$76,650	2	%	2	%
Biologics	29,235	26,863	9	%	9	%
Extremity Fixation	47,409	54,369	(13))%	2	%
Spine Fixation	35,669	43,117	(17))%	(17))%
Total Net Sales	\$190,716	\$200,999	(5))%	(1))%

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	Six Months Ended
June 30,	June 30,

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

	2015	2014	2015	2014
	(%)	(%)	(%)	(%)
Net sales	100	100	100	100
Cost of sales	22	25	22	26
Gross profit	78	75	78	74
Operating expenses:				
Sales and marketing	43	42	46	41
General and administrative	22	18	23	18
Research and development	6	6	6	6
Restatements and related costs	2	2	4	5
Operating income (loss)	5	7	(1)	4
Net income (loss)	4	(1)	(3)	(2)

Three Months Ended June 30, 2015 Compared to Three Months Ended June 30, 2014

Net Sales

Net sales of \$101.0 million in the second quarter of 2015 were flat when compared to the same period in the prior year. Excluding the impact of foreign currency, net sales increased by approximately \$5.1 million, or 5.0%, when compared to the same period in the prior year.

Net Sales by SBU

Net sales in our BioStim SBU increased \$1.2 million, or 3.0%, to \$40.7 million in the second quarter of 2015 compared to \$39.5 million for the same period in the prior year. This increase was primarily due to the continued expansion of the BioStim sales channel.

Net sales in our Biologics SBU increased \$1.4 million, or 10.3%, to \$15.3 million in the second quarter of 2015 compared to \$13.9 million for the same period in the prior year, primarily driven by an expanded sales channel through additional distributors.

Net sales in our Extremity Fixation SBU decreased \$1.7 million, or 6.3%, to \$25.6 million in the second quarter of 2015 compared to \$27.3 million for the same period in the prior year, primarily due to a \$4.9 million decrease from the impact of foreign currency translation, partially offset by an increase in cash collections from customers. Excluding the impact of foreign currency, net sales for our Extremity Fixation SBU increased \$3.2 million, or 11.8%.

Net sales in our Spine Fixation SBU decreased \$0.9 million, or 4.6%, to \$19.4 million in the second quarter of 2015 compared to \$20.3 million for the same period in the prior year, 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

Gross profit increased \$3.5 million, or 4.6%, to \$79.0 million in the second quarter of 2015 compared to \$75.6 million for the same period in the prior year. This increase results from a decrease in costs of sales primarily due to the effects of foreign exchange rates and 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. Gross profit as a percent of net sales was 78.3% in the second quarter of 2015 compared to 74.8% for the same period of the prior year.

Sales and Marketing Expense

Sales and marketing expense increased \$0.9 million, or 2.2%, to \$42.9 million in the second quarter of 2015 compared to \$42.0 million for the same period of the prior year. This increase was primarily driven by an overall increase in sales and field-based training personnel, as part of the rebuilding and expansion of our sales organization. As a percent of net sales, sales and marketing expense was 42.5% in the second quarter of 2015 compared to 41.6% for the same period in the prior year.

General and Administrative Expense

General and administrative expense, inclusive of amortization of intangible assets, increased \$4.3 million, or 23.6%, in the second quarter of 2015 to \$22.5 million compared to \$18.2 million for the same period in the prior year. This increase was primarily driven by \$1.3 million associated with the strengthening of our infrastructure as part of our project "Bluecore," a multi-year, company-wide process and systems improvement initiative to rebuild our infrastructure, \$1.0 million related to a legal judgment, an increase in stock-based compensation of \$0.6 million, as well as increased professional fees and personnel costs within our finance department as part of our internal control remediation efforts. General and administrative expense as a percent of net sales was 22.3% and 18.0%, in the second quarter of 2015 and 2014, respectively.

Research and Development Expense

Research and development expense increased \$0.1 million, or 2.2%, in the second quarter of 2015 to \$6.5 million compared to \$6.3 million for the same period in the prior year. As a percent of net sales, research and development expense was 6.4% in the second quarter of 2015 compared to 6.3% for the same period in the prior year.

Restatements and Related Costs

As part of the restatements of our consolidated financial statements, the Company incurred \$2.2 million of charges related to these activities in the second quarter of 2015 compared to \$2.3 million for the same period in the prior year. The costs incurred in the second 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 second quarter of 2014 are related to our Further Restatement filed in March 2015 and our Original Restatement filed in March 2014.

Interest Income and Expense, Net

Interest income, net was \$0.1 million for the second quarter of 2015 as compared to interest expense, net of \$0.5 million for the same period in the prior year. The increase in interest income was driven by \$0.3 million of interest income relating to the eNeura

Convertible Promissory Note in the second quarter of 2015 and the pay down of all outstanding debt under the Revolving Credit Facility in the third quarter of 2014.

Other Income and Expense

Other income was \$0.9 million for the second quarter of 2015 as compared to \$0.4 million for the same period in the prior year. Other income and expenses include the effect of foreign exchange transactions.

Income Tax Expense

Our effective tax rate on continuing operations was 30.4%, or \$1.8 million, for the second quarter of 2015 as compared to 50.3%, or \$3.3 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 second quarter of 2015 and 2014 was 29.6% and 47.8%, respectively. The principal factors affecting the Company's June 30, 2015 effective tax rate were the Company's mix of earnings among various tax jurisdictions, state taxes, current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit.

Discontinued Operations

Net loss from discontinued operations was approximately \$0.5 million in the second quarter of 2015 as compared to \$3.9 million for the same period in the prior year. These losses are 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.

Six Months Ended June 30, 2015 Compared to Six Months Ended June 30, 2014

Net Sales

Net sales decreased \$10.3 million, or 5.1%, to \$190.7 million in the first six months of 2015 compared to \$201.0 million for the same period in the prior year. Excluding the impact of foreign currency, net sales decreased by \$2.3 million during the first six months of 2015 when compared to the same period in the prior year.

Net Sales by SBU

Net sales in our BioStim SBU increased \$1.8 million, or 2.3%, to \$78.4 million in the first six months of 2015 compared to \$76.7 million for the same period in the prior year. This increase was primarily due to the expansion of the BioStim sales channel.

Net sales in our Biologics SBU increased \$2.4 million, or 8.8%, to \$29.2 million in the first six months of 2015 compared to \$26.9 million for the same period in the prior year, primarily driven by an expanded sales channel through additional distributors.

Net sales in our Extremity Fixation SBU decreased \$7.0 million, or 12.8%, to \$47.4 million in the first six months of 2015 compared to \$54.4 million for the same period in the prior year, primarily due to a \$7.8 million decrease from the impact of foreign currency translation. Excluding the impact of foreign currency, net sales for our Extremity Fixation SBU increased \$0.8 million, or 1.5%.

Net sales in our Spine Fixation SBU decreased \$7.4 million, or 17.3%, to \$35.7 million in the first six months of 2015 compared to \$43.1 million for the same period in the prior year, primarily due to timing of international cash

collections and 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

Gross profit increased \$0.7 million, or 0.4%, to \$149.5 million in the first six months of 2015 compared to \$148.8 million for the same period in the prior year. This increase is due to lower cost of sales primarily due to the effect of foreign exchange rates and 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 the Original Restatement, partially offset by the decrease in sales discussed above. Gross profit as a percent of net sales was 78.4% in the first six months of 2015 and 74.0% in the same period of 2014.

Sales and Marketing Expense

Sales and marketing expense increased \$4.0 million, or 4.9%, to \$87.2 million in the first six months of 2015 compared to \$83.2 million for the same period in the prior year. This increase was primarily driven by 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 commissions quota overachievement in certain territories. As a percent of net sales, sales and marketing expense was 45.7% in the first six months of 2015 compared to 41.4% for the same period in the prior year.

General and Administrative Expense

General and administrative expense, inclusive of amortization of intangible assets, increased \$8.0 million, or 22.2%, in the first six months of 2015 to \$44.1 million compared to \$36.1 million for the same period in the prior year. The majority of the increase in general and an administrative expense was driven by \$3.5 million associated with the strengthening of our infrastructure as part of our project “Bluecore,” a multi-year, company-wide process and systems improvement initiative to rebuild our infrastructure, an increase in stock-based compensation of \$1.2 million, \$1.0 million related to a legal judgment, as well as increased professional fees and personnel costs within our finance department as part of our internal control remediation efforts. General and administrative expense as a percent of net sales was 23.1% compared to 17.9%, in the first six months of 2015 and 2014, respectively.

Research and Development Expense

Research and development expense increased \$0.1 million, or 0.4%, in the first six months of 2015 to \$12.3 million compared to \$12.2 million for the same period in the prior year. As a percent of net sales, research and development expense was 6.4% in the first six months of 2015 compared to 6.1% for the same period in the prior year.

Restatements and Related Costs

As part of our accounting review and restatements of our consolidated financial statements, the Company incurred \$8.1 million of charges related to these activities in the first six months of 2015 compared to \$10.6 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 six 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.

Interest Expense, Net

Interest expense, net was \$0.2 million for the first six months of 2015 compared to \$1.0 million for the same period in the prior year. This decrease was driven by \$0.4 million of interest income related to the eNeura Convertible Promissory Note in the first six months of 2015 and the pay down of all outstanding debt under the Revolving Credit Facility in the third quarter of 2014.

Other Income and Expense

Other income was \$1.5 million for the first six months of 2015 compared to \$0.1 million for the same period in the prior year. The increase 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 partially 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 six months of 2015 as compared to the same period in the prior year.

Income Tax Expense

Our effective tax rate on continuing operations was (298.7)%, or \$2.7 million, for the first six months of 2015 as compared to 77.3%, or \$4.5 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 six months of 2015 and 2014 was (256.6)% and 63.2%, respectively. The principal factors affecting the Company's June 30, 2015 effective tax rate were the Company's mix of earnings among various tax jurisdictions, state taxes, current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit and variations in the customary relationship between income tax expense and pretax earnings.

Discontinued Operations

Net loss from discontinued operations was approximately \$1.1 million in the first six months of 2015 compared to \$4.5 million for the same period in the prior year. These losses are 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

Discussion of Cash Flow

Cash and cash equivalents at June 30, 2015, was \$55.9 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 senior secured credit agreement discussed below.

(Unaudited, U.S. Dollars, in thousands)	Six Months Ended June 30,		
	2015	2014	Year Over Year Change
Net cash provided by operating activities	\$8,954	\$17,874	\$(8,920)
Net cash used in investing activities	(24,026)	(6,225)	(17,801)
Net cash provided by (used in) financing activities	36,124	(11,846)	47,970
Effect of exchange rate changes on cash	(1,921)	192	(2,113)
Net increase (decrease) in cash and cash equivalents	\$19,131	\$(5)	\$19,136

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 \$1.6 million to net loss of \$4.8 million for the six months ended June 30, 2015, from net loss of \$3.2 million for the comparable period in the prior year. Non-cash items for the six months ended June 30, 2015, decreased \$0.3 million to \$14.4 million compared to non-cash items of \$14.7 million in the same period of 2014. Working capital accounts used \$0.6 million of cash for the six months ended June 30, 2015, and provided \$6.4 million for the six months ended June 30, 2014, specifically driven by trade accounts receivable, inventories, and trade accounts payable.

Investing Activities

Net cash used in investing activities increased for the six months ended June 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, partially offset by proceeds from the sale of assets of \$4.8 million.

Financing Activities

Net cash provided by financing activities increased for the six months ended June 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 Revolving Credit Facility and compliance with all required covenants, compared to a balance of \$34.4 million as of December 31, 2014. The December 31, 2014, restricted cash balance represents cash held by subsidiaries that are party to the senior secured credit agreement, and is therefore restricted for use in the U.S. During the six months ended June 30, 2015, and 2014, we also received proceeds of \$1.6 million and \$9.5 million, respectively, from the issuance of 227,840 shares and 432,290 shares, respectively, of our common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

Discussion of Infrastructure Initiative

In 2014, we initiated project Bluecore, a multi-year, company-wide process and systems improvement initiative that is planned to continue through mid-2017, to improve the reliability and efficiency of our systems, processes and reporting as well as drive down our overhead expenses. In addition to re-implementing our Oracle ERP platform 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 six months ended June 30, 2015, the Company spent \$10 million pursuant to this initiative, \$7 million of which was capitalized.

Discussion of Credit Facilities

There have been no material changes to our debt instruments as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014. As of June 30, 2015 there was no outstanding principal under either the Term Loan Facility or the Revolving Credit Facility. Any outstanding balance on the Revolving Credit Facility arising in the event that we draw funds in the

future under such facility would be due on August 30, 2015. The Company is currently in negotiations to renew its revolving credit facility and expects to have this completed prior to the expiration of the current facility.

Other

For information regarding Contingencies, see Note 12 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 5 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

Off-balance Sheet Arrangements

As of June 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 6 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 ~~q~~quoted prices in active markets for identical assets and liabilities

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

Level 3 ~~u~~nobservable 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, restricted cash, 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 restricted cash, 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 June 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 June 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

24

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.

As described in Note 2 to the Financial Statements included in Part I, Item 1 of this Form 10-Q, management has determined that the Unaudited Condensed Consolidated Statement of Cash Flows included in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 contained an immaterial classification error. This error arose because foreign currency exchange rates and cash balances from an incorrect period were used in calculating the line item "Effect of exchange rate changes on cash," which caused the negative effect of such line item to be overstated by \$2.4 million. This resulted in an equal and offsetting error to be reflected in the line item "Net cash provided by operating activities," whereby such line item was overstated by \$2.4 million.

The Company has further evaluated its internal control over financial reporting in relation to this error, including by analyzing the current processes and controls and the breakdown in those processes and controls that caused this error to occur. This analysis included consideration of the nature of the internal control deficiency, its impact on financial reporting, the cause of the control deficiency, how the deficiency and error was identified, and the status of the Company's remediation thereof. Based on this review, the Company has determined that the likelihood that this internal control deficiency could have led to a material error is and was

remote, and is therefore, not the result of any new internal control material weakness distinct from those described above. The Company also believes that this internal control deficiency has been remediated as of June 30, 2015.

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

26

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 demand 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 second 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 12 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 second 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 Employment Agreement, effective as of April 24, 2015, by and between Orthofix Inc. and Doug Rice (filed as an exhibit to the Company’s current report on Form 8-K filed April 29, 2015 and incorporated herein by reference).
- 10.2* Form of Employee Performance Vesting Restricted Stock and Performance Share Unit Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – June 2015 Grants.
- 10.3* Amendment No. 1 to the Orthofix International N.V. 2012 Long-Term Incentive Plan.
- 31.1* Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
- 31.2* Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.

32.1* Section 1350 Certifications of each of the Chief Executive Officer and Chief Financial Officer.

101* The following materials from this Form 10-Q, formatted in Extensible Business Reporting Language (“XBRL”):
(i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Condensed Consolidated Statements of Cash Flows and (iv) related notes, detail tagged.

*Filed herewith.

28

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: August 4, 2015 By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer

Date: August 4, 2015 By: /s/ DOUG RICE
Name: Doug Rice
Title: Chief Financial Officer