ORTHOFIX INTERNATIONAL N V
Form 10-Q
March 31, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from _____ to _____.

Commission File Number: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

Curaçao	**Not applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

7 Abraham de Veerstraat

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

599-9-4658525

(Registrant s telephone number, including area code)

Not applicable

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

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

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

Large Accelerated filer ¨	Accelerated filer x
Non-Accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company ¨

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

As of March 27, 2015, 18,754,831 shares of common stock were issued and outstanding.

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EXPLANATORY NOTE

Orthofix International N.V. (together with its respective consolidated subsidiaries and affiliates, the Company, sometimes referred to as we , us or our) is filing this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014 (this Report) concurrently with the filing of the Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 (2014 Second Quarter Form 10-Q), the amendment (the 2013 Form 10-K/A) to its Annual Report on Form 10-K for the fiscal year ended December 31, 2013 (the Original 2013 Form 10-K) and an amendment (the 2014 First Quarter Form 10-Q/A, and together with the Form 10-K/A, the Amendments) to its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2014 (the Original 2014 First Quarter From 10-Q). As previously disclosed in the Current Report on Form 8-K filed on August 24, 2014, as well as in a Form 12b-25 filed on November 10, 2014, the filing of this Report was delayed while the Company evaluated the accounting treatment applied to certain entries contained in the previous restatement of the Company s prior period financial statements filed in March 2014 (the Original Restatement), as well as related entries in subsequent periods.

As a result of this evaluation, the Company determined that certain manual journal entries with respect to the previously filed consolidated financial statements contained in the Original 2013 Form 10-K and Original 2014 First Quarter Form 10-Q were not properly accounted for under U.S. generally accepted accounting principles (U.S. GAAP). These additional errors affect the fiscal years ended December 31, 2013, 2012 and 2011, as well as the fiscal quarter ended March 31, 2014 and other prior periods. Due to these errors, the Company determined in August 2014 to restate its consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011 (including the interim quarterly periods therein) and the fiscal quarter ended March 31, 2014, and that the previously filed financial statements for these periods should no longer be relied upon. Restated consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011 are contained in the 2013 Form 10-K/A and restated condensed consolidated financial statements for the fiscal quarters ended March 31, 2014 and 2013 are contained in the 2014 First Quarter Form 10-Q/A. In addition, restated condensed consolidated financial statements for the fiscal quarters ended June 30, 2013 are contained in the 2014 Second Quarter Form 10-Q and restated condensed consolidated financial statements for the fiscal quarter ended September 30, 2013 are contained herein. The Company refers to the restated consolidated financial statements for these periods in these collective filings as the Further Restatement.

Description of the Further Restatement

The errors corrected by the Further Restatement are as follows:

A majority of revenue from the Company s BioStim SBU is derived from third parties, which is subject to change due to contractual adjustments related to commercial insurance carriers, and may include certain patient co-pay amounts. The Company previously recorded certain co-pay and self-pay amounts as revenue with estimated uncollectible portions being recognized as bad debt expense. Given the collectability of co-pay and self-pay amounts was not reasonably assured, the conditions for revenue recognition had not been met and revenue for those amounts should not have been recognized until collected. Adjustments to correct the foregoing reduce equally both the Company s historical net sales and its sales and marketing expense by approximately $2.2 million, $9.0 million and $6.0 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, and $1.4 million for the fiscal quarter ended March 31, 2014. Additionally, there was $1.4 million in the fiscal quarter ended March 31, 2014 related to contractual amounts from commercial insurance carriers which was incorrectly classified to bad debt expense rather than a reduction of revenue, for a total reduction to bad debt and revenue of $2.8 million for the fiscal quarter

ended March 31, 2014. These adjustments have no effect on net income from continuing operations or net income in those periods.

Certain bad debt reserves originally recorded in fiscal years 2011 and 2012 were reversed in incorrect periods in the Original Restatement in connection with the change to sell-through accounting for certain distributors. As a result, sales and marketing expense was understated by approximately $1.5 million and $1.1 million for the fiscal years ended December 31, 2013 and 2012, respectively, and overstated by approximately $2.1 million for the fiscal year ended December 31, 2011.

As part of analyzing collections experience on accounts receivable, the Company identified that it had incorrectly considered certain deferred revenue amounts included in gross accounts receivable when calculating estimated reserves. Specifically, the computation of the contractual allowances and bad debt allowances, which serves to adjust accounts receivable to the estimated collectible amount, incorrectly assumed that some percentage of deferred amounts would be collected, rather than fully deferring these amounts. Adjustments to correct this error resulted in a net decrease in operating income of $0.7 million and $0.2 million for the fiscal years ended December 31, 2013 and 2011, respectively, and a net increase in operating income of $2.1 million for the fiscal year ended December 31, 2012, as well as a net decrease in operating loss of $1.5 million for the fiscal quarter ended March 31, 2014.

As part of the Original Restatement, the Company made certain corrections to prior period excess and obsolete inventory reserves. The effect of these corrections was not considered when determining the adjustments needed to eliminate intercompany profits from inventories in the Original Restatement. Adjustments to correct this error resulted in an increase to cost of sales of $1.1 million, $0.2 million and $0.3 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $3.0 million for the fiscal quarter ended March 31, 2014.

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As part of the remediation activities that followed the Original Restatement, the Company expanded its procedures in the second quarter of 2014 to validate the existence of field inventory held by independent sales representatives and noted that, in many cases, this inventory had higher rates of missing inventory (shrinkage) than previously estimated. To determine whether these higher error rates were pervasive across its field inventory, the Company counted approximately 90% of its field inventory during the third and fourth fiscal quarters of 2014. These counts resulted in the identification of errors relating to previous estimates of shrinkage. Adjustments in the Further Restatement to correct these errors, net of the related effect on previously recorded excess and obsolete inventory reserves, resulted in an increase to cost of sales of $0.4 million, $0.3 million and $0.2 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $0.2 million for the fiscal quarter ended March 31, 2014.

In connection with its remediation efforts associated with the material weakness noted in the Original Restatement related to inventory reserves, including performing a hindsight analysis of previously established reserves, the Company concluded that it was not appropriately calculating inventory reserves, including its consideration of demand assumptions for kits , which contain a variety of piece part components to be used during surgery as well as inventory held by third parties under inventory purchase obligations. Adjustments to correct this error resulted in an increase to cost of sales of $3.2 million, $1.5 million and $0.1 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $2.4 million for the fiscal quarter ended March 31, 2014.

In addition to the adjustments described above, the Company is correcting certain other items. The impact of correcting these items results in a decrease to income tax expense of $0.5 million and $1.1 million for the fiscal years ended December 31, 2013 and 2012, respectively to correct an income tax payable error that was recorded during the Original Restatement; these adjustments are separate from the tax effect of the errors described above.

In the aggregate, the remaining additional adjustments resulted in a decrease to loss before income taxes of $1.1 million for the fiscal year ended December 31, 2013, a decrease to income before income taxes of $0.1 million for the fiscal year ended December 31, 2012 and a increase to loss before income taxes of $0.7 million for the fiscal year ended December 31, 2011, as well as a decrease to loss before income taxes of $1.6 million for the fiscal quarter ended March 31, 2014.

Further information regarding the Further Restatement is contained herein and in the Amendments.

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Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to the Company s business and financial outlook, which are based on current assumptions, expectations, estimates, forecasts and projections. In some cases, forward-looking statements can be identified by terminology such as may, will, should, expects, plans, anticipates, estimates, projects, intends, predicts, potential or continue or other comparable terminology. T forward-looking statements are not guarantees of future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from those expressed in these forward-looking statements. Undue reliance should not be placed on these forward-looking statements. The Company undertakes no obligation to further update any such statements to reflect new information, the occurrence of future events or circumstances or otherwise.

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 the recent Audit Committee accounting matters review, the restatements of financial statements for certain prior periods described in the Amendments and herein, and related legal proceedings (including potential action by the Division of Enforcement of the SEC and pending securities class action litigation), the Company s review of allegations of improper payments involving the Company s Brazil-based subsidiary, the Company s previous and current non-compliance with certain Nasdaq Stock Market LLC listing rules, and related pending hearings proceedings in connection therewith, the expected sales of 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 indemnification obligations with respect to certain product liability claims against, and the government investigation of, the Company s former sports medicine global business unit), 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), a deferred prosecution agreement with the U.S. Department of Justice and a consent decree with the SEC, 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 spine and orthopedic industries, credit markets and the economy, corporate development and market development activities, including acquisitions or divestitures, and other risks described in Part I, Item 1A under the heading *Risk Factors* in the 2013 Form 10-K/A, as well as in other reports that the Company will file in the future.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Balance Sheets

(Unaudited, U.S. Dollars, in thousands, except share data)	September 30, 2014	December 31, 2013 (Restated)
Assets		
Current assets:		
Cash and cash equivalents	$ 29,825	$ 28,924
Restricted cash	34,630	23,761
Trade accounts receivable, less allowance for doubtful accounts of $8,118 and $9,111 at September 30, 2014 and December 31, 2013, respectively	62,505	70,811
Inventories	64,266	72,678
Deferred income taxes	39,847	39,999
Prepaid expenses and other current assets	39,272	28,933
Total current assets	270,345	265,106
Property, plant and equipment, net	49,616	54,372
Patents and other intangible assets, net	7,455	9,046
Goodwill	53,565	53,565
Deferred income taxes	21,226	22,394
Other long-term assets	8,838	7,492
Total assets	$ 411,045	$ 411,975
Liabilities and shareholders equity		
Current liabilities:		
Trade accounts payable	$ 13,233	$ 20,674
Other current liabilities	68,148	49,676
Total current liabilities	81,381	70,350
Long-term debt		20,000
Deferred income taxes	12,886	13,026
Other long-term liabilities	11,762	12,736
Total liabilities	106,029	116,112
Contingencies (Note 16)		
Shareholders equity:		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,604,197 and 18,102,335 issued and outstanding as of September 30, 2014 and December 31, 2013, respectively	1,861	1,810

Additional paid-in capital	231,038	216,653
Retained earnings	71,158	73,897
Accumulated other comprehensive income	959	3,503
Total shareholders equity	305,016	295,863
Total liabilities and shareholders equity	$ 411,045	$ 411,975

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

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ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

For the three and nine months ended September 30, 2014 and 2013

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013 (Restated)	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013 (Restated)
Product sales	$ 88,296	$ 80,037	$ 265,175	$ 256,207
Marketing service fees	12,698	11,769	36,818	35,518
Net sales	100,994	91,806	301,933	291,725
Cost of sales	25,268	25,064	77,455	72,789
Gross profit	75,726	66,742	224,538	218,936
Operating expenses				
Sales and marketing	40,998	39,076	124,182	129,459
General and administrative	18,814	12,933	53,643	46,355
Research and development	6,572	6,361	18,818	20,653
Amortization of intangible assets	508	616	1,753	1,725
Costs related to the accounting review and restatement	2,326	2,664	12,959	2,664
Impairment of goodwill		19,193		19,193
	69,218	80,843	211,355	220,049
Operating income (loss)	6,508	(14,101)	13,183	(1,113
Other income and expense				
Interest expense, net	(395)	(539)	(1,355)	(1,536
Other (expense) income, net	(1,322)	(1,481)	(1,231)	2,076
	(1,717)	(2,020)	(2,586)	540
Income (loss) before income taxes	4,791	(16,121)	10,597	(573
Income tax expense	(4,763)	(383)	(9,251)	(7,993
Net income (loss) from continuing operations	28	(16,504)	1,346	(8,566
Discontinued operations (Note 15)				
Income (loss) from discontinued operations	260	(2,375)	(6,363)	(14,427
Income tax benefit (expense)	164	43	2,278	4,593
Net income (loss) from discontinued operations	424	(2,332)	(4,085)	(9,834
Net income (loss)	$ 452	$ (18,836)	$ (2,739)	$ (18,400

et income (loss) per common share-basic:				
et income (loss) from continuing operations, net of tax	$	$ (0.91)	$ 0.07	$ (0.45
et income (loss) from discontinued operations, net of tax	0.02	(0.13)	(0.22)	(0.52
et income (loss) per common share-basic	$ 0.02	$ (1.04)	$ (0.15)	$ (0.97
et income (loss) per common share-diluted:				
et income (loss) from continuing operations, net of tax	$	$ (0.91)	$ 0.07	$ (0.45
et income (loss) from discontinued operations, net of tax	0.02	(0.13)	(0.22)	(0.52
et income (loss) per common share-diluted	$ 0.02	$ (1.04)	$ (0.15)	$ (0.97
eighted average number of common shares:				
asic	18,577,540	18,142,935	18,408,238	18,897,887
luted	18,773,386	18,142,935	18,564,522	18,897,887
ther comprehensive income (loss):				
nrealized (loss) gain on cross-currency swap, net of tax	$ 112	$ 583	$ 184	$ 487
oreign currency translation adjustment	(3,302)	3,206	(2,728)	(184
omprehensive income (loss)	$ (2,738)	$ (15,047)	$ (5,283)	$ (18,097

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

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ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Cash Flows

For the nine months ended September 30, 2014 and 2013

(Unaudited, U.S. Dollars, in thousands)	Nine Months Ended September 30, 2014	2013 (Restated)
Cash flows from operating activities:		
Net loss	$ (2,739)	$ (18,400)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	17,094	15,585
Amortization of debt costs	490	540
Amortization of exclusivity agreements	1,698	1,069
Provision for doubtful accounts	539	2,754
Deferred income taxes	75	(223)
Share-based compensation	4,103	4,714
Impairment of goodwill		19,193
Excess income tax benefit on employee stock-based compensation	(202)	(82)
Other	1,581	(1,165)
Change in operating assets and liabilities:		
Trade accounts receivable	6,118	30,374
Inventories	5,545	(8,777)
Prepaid expenses and other current assets	5,002	6,405
Trade accounts payable	(6,782)	(8,028)
Other current liabilities	3,401	9,485
Long-term assets	66	(1,425)
Long-term liabilities	(23)	(116)
Net cash provided by operating activities	35,966	51,903
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(11,324)	(19,427)
Capital expenditures for intangible assets	(170)	(4,525)
Purchase of other investments	(1,457)	(1,232)
Sale of other investments	32	
Net cash used in investing activities	(12,919)	(25,184)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	10,333	3,431
Repayment of bank borrowings, net		(16)
Repayment of long term debt, net	(20,000)	
Changes in restricted cash	(11,023)	(1,371)
Repurchase of treasury shares		(39,494)
Excess income tax benefit on employee stock-based awards	202	82

Net cash used in financing activities	(20,488)	(37,368)
Effect of exchange rate changes on cash	(1,658)	611
Net increase (decrease) in cash and cash equivalents	901	(10,038)
Cash and cash equivalents at the beginning of the period	28,924	30,767
Cash and cash equivalents at the end of the period	$ 29,825	$ 20,729

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

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ORTHFIX INTERNATIONAL N.V.

Notes to the Unaudited Condensed Consolidated Financial Statements

1. Summary of significant accounting policies

(a) 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 presentation have been included. Operating results for the nine months ended September 30, 2014, are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. The balance sheet at December 31, 2013, has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. For further information, refer to the consolidated financial statements and notes thereto contained in the 2013 Form 10-K/A. The notes to the unaudited condensed consolidated financial statements are presented on a continuing basis unless otherwise noted.

(b) Reclassifications

The Company has reclassified certain line items to conform to the current year presentation. The reclassifications have no effect on previously reported net earnings or shareholders equity.

(c) Use of estimates

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 intangible assets and goodwill impairment, income taxes, and share based compensation. Actual results could differ from these estimates.

(d) Foreign currency translation

The financial statements for operations outside the U.S. are generally maintained in their local currency. All foreign currency denominated balance sheet accounts, except shareholders equity, are translated to U.S. dollars at period end exchange rates and revenue and expense items are translated at weighted average rates of exchange prevailing during the year. Gains and losses resulting from the translation of foreign currency are recorded in the accumulated other comprehensive income component of shareholders equity.

(e) Collaborative agreement

The Company receives a marketing fee through collaboration with Musculoskeletal Transplant Foundation (MTF) for Trinity Evolution® and Trinity ELITE®, for which, the Company has exclusive marketing rights, and VersaShield for which we have non-exclusive marketing rights. Under the agreements with MTF, MTF processes the tissues, maintains inventory, and invoices hospitals and surgery centers and other points of care for service fees, which are

submitted by customers via purchase orders. MTF is considered the primary obligor in these arrangements and therefore the Company recognizes these marketing service fees on a net basis upon shipment of the product to the customer.

(f) Recently issued accounting standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 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. ASU 2014-09 is effective for the Company in the fiscal year beginning on January 1, 2017, including interim periods within that reporting period and is to be applied retrospectively, with early application not permitted. The Company is currently evaluating the effect that adopting this new accounting guidance will have on consolidated results of operations, cash flows and financial position.

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2. Original and Further Restatement of the Consolidated Financial Statements

In connection with the Company s preparation of its consolidated interim quarterly financial statements for the fiscal quarter ended June 30, 2014, the Company determined that certain entries with respect to the previously filed financial statements contained in the Original 2013 Form 10-K and the Original 2014 First Quarter Form 10-Q were not properly accounted for under U.S. generally accepted accounting principles (U.S. GAAP). As further described below, these additional errors affect the fiscal years ended December 31, 2013, 2012 and 2011, as well as the fiscal quarter ended March 31, 2014. Due to these errors, the Company determined in August 2014 to restate its consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011 (including the interim quarterly periods contained within the fiscal years ended December 31, 2013 and 2012) and the fiscal quarter ended March 31, 2014, and that the previously filed financial statements for these periods should no longer be relied upon. This Report contains restated consolidated interim financial statements for the fiscal quarter and year-to-date periods ended September 30, 2013.

Contemporaneously with the filing of this Report, the Company is filing (i) an amendment to the Original 2013 Form 10-K (the 2013 Form 10-K/A), which amendment contains restated consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011, and the quarterly reporting periods contained within the fiscal years ended December 31, 2013 and 2012, (ii) an amendment to the Original 2014 First Quarter Form 10-Q for the fiscal quarter ended March 31, 2014 (the 2014 First Quarter Form 10-Q/A), which amendment contains restated consolidated interim financial statements for the fiscal quarters ended March 31, 2014 and 2013, and (iii) its delayed Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2014 (the 2014 Second Quarter Form 10-Q), which contains restated consolidated interim financial statements for the fiscal quarterly and year-to-date periods ended June 30, 2013. The corrections of the additional errors in the 2013 Form 10-K/A and the 2014 First Quarter Form 10-Q/A are referred to herein as the Further Restatement.

The Original 2013 Form 10-K reflected a prior restatement of the Company s consolidated financial statements for the fiscal years ended December 31, 2012 and 2011 and the fiscal quarter ended March 31, 2013, which we refer to herein as the Original Restatement. For additional information regarding the Original Restatement, see the 2013 Form 10-K/A.

Background of Further Restatement

During the second quarter of 2014, the Company s management noted that the Company s bad debt expense for its BioStim strategic business unit (SBU) during the first quarter of 2014 was higher than internally budgeted. As a result, the Company s internal finance department reviewed bad debt expense entries in prior periods. In connection with this review, the Company also further considered its accounting methodology with respect to certain prior revenue adjustments related to uncollectible patient co-pay and self-pay amounts. As further described below, after performing this review, the Company determined that errors existed relating to the accounting for uncollectible patient co-pay and self-pay amounts, and that certain bad debt reserves originally recorded in fiscal years 2011 and 2012 were reversed in incorrect periods in the Original Restatement in connection with the change to sell-through accounting for certain distributors. After analyzing these errors, the Company determined to further restate its financial statements as described in the 2013 Form 10-K/A, the 2014 First Quarter Form 10-Q/A and herein. In addition to these matters, certain other adjustments identified by management, including revisions to inventory reserves, intercompany profit adjustments and accounts receivable reserves, were made to the consolidated financial statements in connection with the Further Restatement, as discussed below.

Co-Pay and Self-Pay Revenue Adjustments

A majority of revenue from the Company s BioStim SBU is derived from third parties, which is subject to change due to contractual adjustments related to commercial insurance carriers, and may include certain patient co-pay amounts. In addition, certain patient purchasers are without insurance, with revenue derived from self-pay arrangements. In previously issued financial statements, the Company recorded these co-pay and self-pay amounts as revenue with estimated uncollectible portions being recognized as bad debt expense. Upon further analysis, it was determined that because collectability of co-pay and self-pay amounts was not reasonably assured, the conditions for revenue recognition had not been met and revenue for those amounts should not have been recognized until collected.

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Adjustments to correct the foregoing reduce equally both the Company s historical net sales and its sales and marketing expense by approximately $1.2 million and $3.0 million for the fiscal quarter ended September 30, 2013 and the nine months ended September 30, 2013, respectively. These adjustments have no effect on net income from continuing operations, net income or total assets in any period.

Bad Debt Timing Adjustments

In connection with the foregoing, the Company determined to review bad debt expense trends more broadly across all of its business units. As a result of this process, the Company determined that certain bad debt reserves originally recorded in fiscal years 2011 and 2012 were reversed in incorrect periods in the Original Restatement in connection with the change to sell-through accounting for certain distributors. Because the Original Restatement transferred these transactions to sell-through accounting (as opposed to sell-in accounting, which had been used when the original bad debt reserves were recorded), the bad debt reserve was reversed as part of the Original Restatement, as the receivable that was being reserved for was no longer recognized.

Adjustments to correct this error result in an increase of sales and marketing expense of $1.5 million for the nine months ended September 30, 2013. There were no adjustments to the fiscal quarter ended September 30, 2013. These adjustments resulted in no impact to the accounts receivable balance as of December 31, 2013.

Accounts Receivable Reserve Adjustments

As part of analyzing collections experience on accounts receivable, the Company identified that it had incorrectly considered certain deferred revenue amounts included in gross accounts receivable when calculating estimated reserves. Specifically, the computation of the contractual allowances and bad debt allowances, which serves to adjust accounts receivable to the estimated collectible amount, incorrectly assumed that some percentage of the deferred amounts would be collected, rather than fully deferring these amounts.

Adjustments to correct this error resulted in a net increase in operating income of $0.2 million and $0.3 million for the fiscal quarter and nine months ended September 30, 2013, respectively.

This adjustment resulted in a decrease in accounts receivable, net (due to an increase in reserves) as of December 31, 2013 by $4.2 million.

Intercompany Profit Adjustments

The Company has two manufacturing facilities which support the inventory needs of other subsidiaries through intercompany sales transactions. These intercompany sales include a profit margin for the selling subsidiary (intercompany profit) that is eliminated by the Company as part of its consolidated financial reporting process. The elimination of intercompany profit requires determining the affected net inventory amounts and their related intercompany profit margin to eliminate all intercompany profit, resulting in all inventories being carried at historical cost in the Company s consolidated financial statements.

As part of the Original Restatement the Company made certain corrections to prior period excess and obsolete inventory reserves. The effect of these corrections was not properly considered when determining the adjustments needed to eliminate intercompany profits from inventories in the Original Restatement.

Adjustments to correct this error resulted in an increase to cost of sales of $0.8 million and $1.0 million for the fiscal quarter ended September 30, 2013 and the nine months ended September 30, 2013, respectively.

This adjustment resulted in a decrease in inventory as of December 31, 2013 by $2.6 million.

Inventory

Inventory Existence

As part of the remediation activities that followed the Original Restatement, the Company expanded its procedures in the second quarter of 2014 to validate the existence of field inventory held by independent sales representatives and noted that, in many cases, this inventory had higher rates of missing inventory (shrinkage) than previously estimated. To determine whether these higher error rates were pervasive across its field inventory, the Company counted approximately 90% of its field inventory during the third and fourth fiscal quarters of 2014. These counts resulted in the identification of errors relating to previous estimates of shrinkage.

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Adjustments in the Further Restatement to correct these errors, net of the related effect on previously recorded excess and obsolete inventory reserves, resulted in an increase to cost of sales of $0.2 million and $0.3 million for the fiscal quarter and nine months ended September 30, 2013, respectively.

These adjustments resulted in a decrease in inventory as of December 31, 2013 by $1.0 million.

Inventory Reserves

In connection with its remediation efforts associated with the material weakness noted in the Original Restatement related to inventory reserves, the Company concluded that it was not appropriately calculating inventory reserves, including its consideration of demand assumptions for kits , which contain a variety of piece part components to be used during surgery that have various demand considerations, as well as inventory held by third parties under inventory purchase obligations.

Adjustments to correct these errors resulted in an increase to cost of sales of $1.1 million and $3.1 million for the fiscal quarter ended September 30, 2013 and the nine months ended September 30, 2013, respectively. These adjustments resulted in a decrease to inventory (due to an increase in reserves) as of December 31, 2013 by $14.4 million.

Other Adjustments

In addition to the adjustments described above, the Company is correcting certain other items. The impact of correcting these items results in a decrease to loss before income taxes of $3.4 million and $3.2 million for the fiscal quarter and nine months ended September 30, 2013, respectively.

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The tables below show the effects of the Further Restatement for the fiscal quarter ended September 30, 2013 and the nine months ended September 30, 2013. The tax effect of the adjustments is estimated based on the Company s estimated tax rate.

Three Months Ended September 30, 2013
Further Restatement Adjustments by Category

(U.S. Dollars, in thousands)	Originally Reported in 2013 Form 10-Q	Co-Pay and Self-Pay Revenue	Bad Debt Timing	Accounts Receivable Reserve	Intercompany Profit	Inventory	Other	Total Further Restatement Adjustments	Restated
Net sales	$ 92,738	$ (1,191)	$	$ 240	$	$	$ 19	$ (932)	$ 91,806
Cost of sales	23,920				770	1,320	(946)	1,144	25,064
Gross profit	68,818	(1,191)		240	(770)	(1,320)	965	(2,076)	66,742
Operating expenses									
Sales and marketing	42,382	(1,191)		14			(2,129)	(3,306)	39,076
General and administrative	13,202						(269)	(269)	12,933
Research and development	6,361								6,361
Amortization of intangible assets	616								616
Costs related to the accounting review and restatement	2,664								2,664
Impairment of goodwill	19,193								19,193
	84,418	(1,191)		14			(2,398)	(3,575)	80,843
Operating (loss) income	(15,600)			226	(770)	(1,320)	3,363	1,499	(14,101)
Other income and (expense)	(2,036)						16	16	(2,020)
Loss before income taxes	(17,636)			226	(770)	(1,320)	3,379	1,515	(16,121)
Income tax expense	(448)			(79)	(270)	462	(588)	65	(383)
Net loss from continuing operations	$ (18,084)	$	$	$ 147	$ (500)	$ (850)	$ 2,791	$ 1,580	$ (16,504)

Nine Months Ended September 30, 2013
Further Restatement Adjustments by Category

(U.S. Dollars, in thousands)	Originally Reported in 2013 Form 10-Q	Co-Pay and Self-Pay Revenue	Bad Debt Timing	Accounts Receivable Reserve	Intercompany Profit	Inventory	Other	Total Further Restatement Adjustments	Restated
Net sales	$ 294,391	$ (2,980)	$	$ 364	$	$	$ (50)	$ (2,666)	$ 291,725
Cost of sales	69,783				1,012	3,399	(1,405)	3,006	72,789

Gross profit	224,608	(2,980)		364	(1,012)	(3,399)	1,355	$ (5,672)	218,936
Operating expenses									
Sales and marketing	132,346	(2,980)	1,455	54			(1,416)	(2,887)	129,459
General and administrative	46,736						(381)	(381)	46,355
Research and development	20,653								20,653
Amortization of intangible assets	1,725								1,725
Costs related to accounting review and restatement	2,664								2,664
Impairment of goodwill	19,193								19,193
	223,317	(2,980)	1,455	54			(1,797)	(3,268)	220,049
Operating income	1,291		(1,455)	310	(1,012)	(3,399)	3,152	(2,404)	(1,113)
Other income and (expense)	491						49	49	540
Loss before income taxes	1,782		(1,455)	310	(1,012)	(3,399)	3,201	(2,355)	(573)
Income tax expense	(8,126)		509	(109)	354	1,190	(1,811)	133	(7,993)
Net loss from continuing operations	$ (6,344)	$	$ (964)	$ 201	$ (658)	$ (2,209)	$ 1,390	$ (2,222)	$ (8,566)

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The effects of the Further Restatement on the condensed consolidated balance sheet as of December 31, 2013 are as follows:

	As of December 31, 2013		
(Unaudited, U.S. Dollars, in thousands, except share data)	Originally Reported in 2013 Form 10-K	Further Restatement Adjustments	Restated
Assets			
Current assets:			
Cash and cash equivalents	$ 30,486	$ (1,562)	$ 28,924
Restricted cash	23,761		23,761
Trade accounts receivable, less allowances of $9,111 at December 31, 2013	75,567	(4,756)	70,811
Inventories	90,577	(17,899)	72,678
Deferred income taxes	33,947	6,052	39,999
Prepaid expenses and other current assets	25,906	3,027	28,933
Total current assets	280,244	(15,138)	265,106
Property, plant and equipment, net	54,606	(234)	54,372
Patents and other intangible assets, net	9,046		9,046
Goodwill	53,565		53,565
Deferred income taxes	18,336	4,058	22,394
Other long-term assets	7,385	107	7,492
Total assets	$ 423,182	$ (11,207)	$ 411,975
Liabilities and shareholders equity			
Current liabilities:			
Trade accounts payable	$ 20,674	$	$ 20,674
Other current liabilities	46,146	3,530	49,676
Total current liabilities	66,820	3,530	70,350
Long-term debt	20,000		20,000
Deferred income taxes	13,132	(106)	13,026
Other long-term liabilities	12,736		12,736
Total liabilities	112,688	3,424	116,112
Contingencies (Note 16)			
Shareholders equity:			
Common shares $0.10 par value; 50,000,000 shares authorized; 18,102,335 issued and outstanding as of December 31, 2013	1,810		1,810
Additional paid-in capital	216,653		216,653
Retained earnings	89,332	(15,435)	73,897
Accumulated other comprehensive income	2,699	804	3,503

Total shareholders equity	310,494	(14,631)	295,863
Total liabilities and shareholders equity	$ 423,182	$ (11,207)	$ 411,975

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The effects of the Further Restatement on the condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2013 are as follows:

	Three Months Ended September 30, 2013		
(Unaudited, U.S. Dollars, in thousands, except share and per share data)	**Originally Reported in 2013 Form 10-Q**	**Further Restatement Adjustments**	**Restated**
Product sales	$ 81,061	$ (1,024)	$ 80,037
Marketing service fees	11,677	92	11,769
Net sales	92,738	(932)	91,806
Cost of sales	23,920	1,144	25,064
Gross profit	68,818	(2,076)	66,742
Operating expenses			
Sales and marketing	42,382	(3,306)	39,076
General and administrative	13,202	(269)	12,933
Research and development	6,361		6,361
Amortization of intangible assets	616		616
Costs related to the accounting review and restatement	2,664		2,664
Impairment of goodwill	19,193		19,193
	84,418	(3,575)	80,843
Operating loss	(15,600)	1,499	(14,101)
Other income and expense			
Interest expense, net	(555)	16	(539)
Other expense	(1,481)		(1,481)
	(2,036)	16	(2,020)
Loss before income taxes	(17,636)	1,515	(16,121)
Income tax expense	(448)	65	(383)
Net loss from continuing operations	(18,084)	1,580	(16,504)
Discontinued operations (Note 15)			
Loss from discontinued operations	(3,041)	666	(2,375)
Income tax benefit	1,303	(1,260)	43
Net loss from discontinued operations, net of tax	(1,738)	(594)	(2,332)
Net loss	$ (19,822)	$ 986	$ (18,836)
Net loss per common share-basic:			

Net loss from continuing operations, net of tax	$ (1.00)	$ 0.09	$ (0.91)
Net loss from discontinued operations, net of tax	(0.10)	(0.03)	(0.13)
Net loss per common share-basic	$ (1.10)	$ 0.06	$ (1.04)
Net loss per common share-diluted:			
Net loss from continuing operations, net of tax	$ (1.00)	$ 0.09	$ (0.91)
Net loss from discontinued operations, net of tax	(0.10)	(0.03)	(0.13)
Net loss per common share-diluted	$ (1.10)	$ 0.06	$ (1.04)
Weighted average number of common shares:			
Basic	18,142,935		18,142,935
Diluted	18,142,935		18,142,935
Comprehensive loss	$ (16,064)	$ 1,017	$ (15,047)

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(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Nine Months Ended September 30, 2013 Originally Reported in 2013 Form 10-Q	Further Restatement Adjustments	Restated
Product sales	$ 259,030	$ (2,823)	$ 256,207
Marketing service fees	35,361	157	35,518
Net sales	294,391	(2,666)	291,725
Cost of sales	69,783	3,006	72,789
Gross profit	224,608	(5,672)	218,936
Operating expenses			
Sales and marketing	132,346	(2,887)	129,459
General and administrative	46,736	(381)	46,355
Research and development	20,653		20,653
Amortization of intangible assets	1,725		1,725
Costs related to the accounting review and restatement	2,664		2,664
Impairment of goodwill	19,193		19,193
	223,317	(3,268)	220,049
Operating income (loss)	1,291	(2,404)	(1,113)
Other income and expense			
Interest expense, net	(1,585)	49	(1,536)
Other income	2,076		2,076
	491	49	540
Income (loss) before income taxes	1,782	(2,355)	(573)
Income tax expense	(8,126)	133	(7,993)
Net loss from continuing operations	(6,344)	(2,222)	(8,566)
Discontinued operations (Note 15)			
Loss from discontinued operations	(16,629)	2,202	(14,427)
Income tax benefit	5,334	(741)	4,593
Net loss from discontinued operations	(11,295)	1,461	(9,834)
Net loss	$ (17,639)	$ (761)	$ (18,400)
Net loss per common share-basic:			
Net loss from continuing operations	$ (0.34)	$ (0.11)	$ (0.45)
Net loss from discontinued operations	(0.60)	0.08	(0.52)
Net loss per common share-basic	$ (0.94)	$ (0.03)	$ (0.97)

Net loss per common share-diluted:			
Net loss from continuing operations	$ (0.34)	$ (0.11)	$ (0.45)
Net loss from discontinued operations	(0.60)	0.08	(0.52)
Net loss per common share-diluted	$ (0.94)	$ (0.03)	$ (0.97)
Weighted average number of common shares:			
Basic	18,897,887		18,897,887
Diluted	18,897,887		18,897,887
Comprehensive loss	$ (17,426)	$ (671)	$ (18,097)

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The effects of the Further Restatement on the condensed consolidated statement of cash flows for the nine months ended September 30, 2013 are as follows:

	Nine Months Ended September 30, 2013		
(Unaudited, U.S. Dollars, in thousands)	**Originally Reported in 2013 Form 10-Q**	**Further Restatement Adjustments**	**Restated**
Cash flows from operating activities:			
Net loss	$ (17,639)	$ (761)	$ (18,400)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation and amortization	15,459	126	15,585
Amortization of debt costs	540		540
Amortization of exclusivity agreements		1,069	1,069
Provision for doubtful accounts	4,225	(1,471)	2,754
Deferred income taxes	(223)		(223)
Share-based compensation	4,714		4,714
Impairment of goodwill	19,193		19,193
Excess income tax benefit on employee stock-based awards	(82)		(82)
Other	(520)	(645)	(1,165)
Change in operating assets and liabilities:			
Trade accounts receivable	27,758	2,616	30,374
Inventories	(11,596)	2,819	(8,777)
Prepaid expenses and other current assets	5,541	864	6,405
Trade accounts payable	(8,028)		(8,028)
Other current liabilities	13,040	(3,555)	9,485
Long-term assets	482	(1,907)	(1,425)
Long-term liabilities	(912)	796	(116)
Net cash provided by operating activities	51,952	(49)	51,903
Cash flows from investing activities:			
Capital expenditures for property, plant and equipment	(19,427)		(19,427)
Capital expenditures for intangible assets	(4,525)		(4,525)
Purchase of other investments		(1,232)	(1,232)
Net cash used in investing activities	(23,952)	(1,232)	(25,184)
Cash flows from financing activities:			
Net proceeds from issuance of common shares	3,431		3,431
(Repayment of) proceeds from bank borrowings, net	(16)		(16)
Changes in restricted cash	(1,371)		(1,371)
Repurchase of treasury shares	(39,494)		(39,494)
	82		82

Excess income tax benefit on employee stock-based awards			
Net cash used in financing activities	(37,368)		(37,368)
Effect of exchange rate changes on cash	532	79	611
Net decrease in cash and cash equivalents	(8,836)	(1,202)	(10,038)
Cash and cash equivalents at the beginning of the period	31,055	(288)	30,767
Cash and cash equivalents at the end of the period	$ 22,219	(1,490)	$ 20,729

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3. Inventories

The Company s inventories are primarily stated at standard cost, which approximates actual cost determined on a first-in, first-out basis. The Company adjusts the value of its inventory to the extent management determines that the cost cannot be recovered due to obsolescence or other factors. In order to make these determinations, management uses estimates of future demand and sales prices for each product to determine the appropriate inventory reserves and to make corresponding adjustments to the carrying value of these inventories to reflect the lower of cost or market value. In the event of a sudden significant decrease in demand for the Company s products, or a higher incidence of inventory obsolescence, the Company could be required to increase its inventory reserves, which would increase cost of sales and decrease gross profit.

Work-in-process and finished products include material, labor and production overhead costs. Deferred cost of sales result from certain 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 deferred revenues and associated cost of sales are recognized.

Inventories were as follows:

(U.S. Dollars, in thousands)	September 30, 2014	December 31, 2013 (Restated)
Raw materials	$ 4,211	$ 6,515
Work-in-process	5,690	6,606
Finished products	47,938	51,991
Deferred cost of sales	6,427	7,566
Total Inventory	$ 64,266	$ 72,678

4. Patents and other intangible assets

(U.S. Dollars, in thousands)	September 30, 2014	December 31, 2013
Cost		
Patents	$ 35,288	$ 34,820
Trademarks definite lived	607	620
Licenses and other	7,248	7,748
	43,143	43,188
Accumulated amortization		
Patents	(33,002)	(31,739)
Trademarks definite lived	(485)	(454)
Licenses and other	(2,201)	(1,949)
	(35,688)	(34,142)

Patents and other intangible assets, net	$	7,455	$	9,046

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5. Goodwill

As a result of the Company s change in reporting structure in July of 2013, the Company allocated goodwill to each reporting unit, and subsequently evaluated all reporting units, including the Extremity Fixation and Spine Fixation reporting units, for the possible impairment of goodwill. The result of this evaluation was a full impairment of the goodwill allocated to the Extremity Fixation and Spine Fixation reporting units, totaling $19.2 million. As of December 31, 2013 and September 30, 2014, accumulated impairment was $9.8 million for the Extremity Fixation reportable unit and $9.4 million for the Spine Fixation reporting unit. The BioStim and Biologics reportable units have not been impaired. The following table presents the net carrying value of goodwill by reportable segment as of September 30, 2014 and December 31, 2013.

(U.S. Dollars, in thousands)	September 30, 2014	December 31, 2013
BioStim	$ 42,678	$ 42,678
Biologics	10,887	10,887
Total goodwill	$ 53,565	$ 53,565

6. Bank borrowings

The Company had no borrowings and an unused available line of credit of 5.8 million ($7.3 million and $8.0 million) at September 30, 2014 and December 31, 2013, respectively, in its Italian line of credit. This line of credit provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing. This line of credit is unsecured.

7. 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 provides 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 December 31, 2013, there was $20 million outstanding under the Revolving Credit Facility, which was paid in its entirety along with applicable interest in September of 2014. Borrowings under the Credit Facilities bear interest at a floating rate, which is, at Orthofix Holdings option, either the London Inter-Bank Offered Rate (LIBOR) plus an applicable margin or a base rate (as defined in the Credit Agreement) plus an applicable margin (in each case subject to adjustment based on financial ratios). Such applicable margin will be up to 3.25% for LIBOR borrowings and up to 2.25% for base rate borrowings depending upon a measurement of the consolidated leverage ratio with respect to the immediately preceding four fiscal quarters. As of September 30, 2014, and December 31, 2013, the entire Revolving Credit Facility was at the LIBOR rate plus a margin of 2.50%. The effective interest rate on the Credit Facilities as of September 30, 2014, and December 31, 2013, was 2.7%. Any outstanding balances on the Revolving Credit Facility

are due on August 30, 2015.

Borrowings under the Revolving Credit Facility, which may be made in the future, may be used for working capital, capital expenditures and other general corporate purposes of Orthofix Holdings and its subsidiaries. The Guarantors have guaranteed repayment of Orthofix Holdings obligations under the Credit Agreement. The obligations of Orthofix Holdings and each of the Guarantors with respect to the Credit Facilities are secured by a pledge of substantially all of the assets of Orthofix Holdings and each of the Guarantors.

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The Credit Agreement, as amended, requires Orthofix Holdings and the Company to comply with coverage ratios on a consolidated basis and contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. The Credit Agreement, as amended, also includes events of default customary for facilities of this type. Upon the occurrence of an event of default, all outstanding loans may be accelerated and/or the lenders commitments terminated. On August 14, 2013, the Company entered into a Limited Waiver (the Original Limited Waiver) with the lenders under the Credit Agreement (the Lenders) which waived requirements under the Credit Agreement to deliver quarterly financial statements for the fiscal quarter ended on September 30, 2013, and related financial covenant certificates, until the earlier of (i) March 31, 2014 or (ii) the date that is one day after such financial statements are publicly filed or released. The Company was in compliance with the affirmative and negative covenants at September 30, 2014 and there were no events of default.

In connection with the Further Restatement and the Company s delay in filing this Report, on August 14, 2014 the Company entered into a subsequent Limited Waiver with the Lenders, which was extended on September 30, 2014, January 15, 2015 and February 26, 2015 (the Subsequent Limited Waivers). Under the Subsequent Limited Waivers, the Lenders collectively waived requirements under the Credit Agreement that the Company deliver quarterly financial statements with respect to the fiscal quarters ended June 30, 2014 and September 30, 2014, and related financial covenant certificates, until the earlier of (i) March 31, 2015 or (ii) the date that is one day after such financial statements are publicly filed or released. The Subsequent Limited Waivers also extend the date by which the Company is required to provide certain 2014 fiscal year financial statements until the earlier of (i) one business day following the date that the Company files its Annual Report on Form 10-K for the fiscal year ended December 31, 2014 or (ii) April 30, 2015. In addition, the Subsequent Limited Waivers provided that the Further Restatement would not constitute a default or event of default provided that within one business day after the public release or filing of such restated financial statements, the Company delivered corrected financial statements and compliance certificates with respect to such restated periods and immediately paid any additional interest and other fees that would have been owed had applicable interest and fees originally been calculated based on the restated financial statements. As of the date hereof, the Company has delivered the quarterly consolidated financial statements for the fiscal quarters ended June 30, 2014 and September 30, 2014, and the Company does not expect the Further Restatement to trigger any such additional interest or fees with respect to such prior periods. However, in the event that the Company does not satisfy these respective obligations under the Subsequent Limited Waivers and/or the Credit Agreement, an event of default could be declared under the Credit Agreement, which could have a material adverse effect on the Company s financial position.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company s Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes.

The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of September 30, 2014, and December 31, 2013, is $178.6 million and $168.5 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities from access to cash held by Orthofix Holdings, Inc. and its subsidiaries. All of the Company s subsidiaries that are parties to the Credit Agreement have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of September 30, 2014, and December 31, 2013, was $34.6 million and $23.8 million, respectively.

In conjunction with obtaining the Credit Facilities and the Credit Agreement, as amended, the Company incurred debt issuance costs of $5 million. These costs are being amortized using the effective interest method over the life of the Credit Facilities. In conjunction with the Term Loan Facility repayment in May 2012, the Company wrote off $0.8 million of related debt issuance costs. As of September 30, 2014, and December 31, 2013, debt issuance costs, net of

accumulated amortization, related to the Credit Agreement were $0.6 million and $1.1 million, respectively.

8. 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) (OCI) or net income (loss).

(U.S. Dollars, in thousands)

As of September 30, 2014	Fair value: favorable (unfavorable)	Balance sheet location
Cross-currency swap	$ 1,838	Other long-term assets
Warrants	$ 329	Other long-term assets
As of December 31, 2013		
Cross-currency swap	$ (1,036)	Other long-term liabilities
Warrants	$ 107	Other long-term assets

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(U.S. Dollars, in thousands)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Cross-currency swap and warrants unrealized gain (loss) recorded in other comprehensive income (loss), net of taxes	$ 112	$ 583	$ 184	$ 487

Cross-currency swap

On September 30, 2010, the Company entered into a cross-currency swap agreement (the replacement swap agreement) with JPMorgan Chase Bank and Royal Bank of Scotland PLC (the counterparties) to manage its cash flows related to foreign currency exposure for a portion of the Company s intercompany receivable of a U.S. dollar functional currency subsidiary that is denominated in Euro.

Under the terms of the swap agreement, the Company pays Euros based on a 28.7 million notional value and a fixed rate of 5.00% and receives U.S. dollars based on a notional value of $39 million and a fixed rate of 4.635%. The expiration date is December 30, 2016, the date upon which the underlying intercompany debt, to which the swap agreement applies, matures. The swap agreement is designated as a cash flow hedge and therefore the Company recognized an unrealized gain (loss) on the change in fair value, net of tax, within other comprehensive income (loss).

Warrants

In 2013 and 2014, the Company purchased notes receivable from Bone Biologics, Inc. (Bone Biologics) totaling $750 thousand, all of which were issued with detachable warrants to purchase common stock of Bone Biologics. In addition, on July 1, 2014, the Company purchased 500 thousand shares of Bone Biologics for $500 thousand in a stock subscription agreement, resulting in a total investment in Bone Biologics as of September 30, 2014 of $1.25 million. As of December 31, 2013, the Company held warrants for 125 thousand shares of Bone Biologics, at an exercise price of $1.00 per share. As of September 30, 2014, the Company held warrants for 458 thousand shares of Bone Biologics, with a weighted average exercise price of $1.36 per share.

Under the terms of the note and warrant purchase agreements, the warrants to purchase common stock in Bone Biologics are both detachable from the note, exercisable over a seven year period, and transferable by the holder to other parties.

9. 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	quoted prices in active markets for identical assets and liabilities
Level 2	observable inputs other than quoted prices in active markets for identical assets and liabilities
Level 3	unobservable 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, certificates of deposit, treasury securities, collective trust funds, trade accounts receivable, other investments, accounts payable, long-term secured debt, deferred compensation plan liabilities and derivative securities. The carrying value of restricted cash, accounts receivable 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.

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The Company s collective trust funds, treasury securities, certificates of deposit, deferred compensation plan liabilities and derivative securities are the only financial instruments recorded at fair value on a recurring basis. The fair value of treasury securities and certificates of deposit are determined based on quoted prices in active markets for identical assets, therefore, the Company has categorized these instruments as Level 1 financial instruments. The cross-currency derivative instrument consists of an over-the-counter contract, which is not traded on a public exchange. The fair value of this derivative swap contract, the common stock warrants, other investments, the Company s collective trust funds and the Company s deferred compensation plan liabilities are determined based on inputs that are readily available in public markets or can be derived from information available in publicly quoted markets, therefore, the Company has categorized these instruments as Level 2 financial instruments. Changes in the fair value of collective trust funds and deferred compensation plan liabilities are recorded in Other income (expense). The Company also considers counterparty credit risk and its own credit risk in its determination of estimated fair values. The Company has consistently applied these valuation techniques in all periods presented.

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

(U.S. Dollars in thousands)	Balance September 30, 2014	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 1,635	$	$ 1,635	$
Treasury securities	610	610		
Certificates of deposit	1,595	1,595		
Derivative securities	2,167		2,167	
Other investments	1,250		1,250	
Total	$ 7,257	$ 2,205	$ 5,052	$
Liabilities				
Deferred compensation plan	$ (1,927)	$	$ (1,927)	$
Total	$ (1,927)	$	$ (1,927)	$

(U.S. Dollars in thousands)	Balance December 31, 2013	Level 1	Level 2 (Restated)	Level 3
Assets				
Collective trust funds	$ 1,667	$	$ 1,667	$
Treasury securities	660	660		
Certificates of deposit	1,562	1,562		
Derivative securities	107		107	
Total	$ 3,996	$ 2,22 2	$ 1,774	$

Liabilities				
Deferred compensation plan	$ (2,506)	$	$ (2,506)	$
Derivative securities				
Cross-currency hedge	(1,036)		(1,036)	
Total	$ (3,542)	$ (2,506)	$ (3,542)	$

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10. Accumulated other comprehensive income

Accumulated other comprehensive income (loss) is primarily 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 income were as follows:

(U.S. Dollars, in thousands)	Foreign Currency Translation Adjustments (Restated)	Market to Market on Financial Instruments (Restated)	Accumulated Other Comprehensive Loss (Restated)
Balance at December 31, 2013	$ 3,651	$ (148)	$ 3,503
Unrealized loss on cross-currency swap and warrants, net of tax		184	184
Foreign currency translation adjustment (1)	(2,728)		(2,728)
Balance at September 30, 2014	$ 923	$ 36	$ 959

(1) As undistributed earnings of non-U.S. dollar denominated foreign subsidiaries are indefinitely reinvested, no deferred taxes are recognized on the related foreign currency translation adjustment.

11. Earnings per share

For the three and nine months ended September 30, 2014 and 2013, 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 income (loss) per common share computations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Weighted average common shares-basic	18,577,540	18,142,935	18,408,238	18,897,887
Effect of dilutive securities:				
Unexercised stock options net of treasury share repurchase	195,846		156,284	
Weighted average common shares-diluted	18,773,386	18,142,935	18,564,522	18,897,887

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 1,023,038 and 1,055,422 outstanding options not included in the diluted earnings per share computation for the three and nine months ended September 30, 2014, respectively, because the inclusion of these options was antidilutive. There were 1,647,878 and

1,186,259 outstanding options not included, respectively, in the diluted earnings per share computation for the three and nine months ended September 30, 2013, respectively, because the inclusion of these options was anti-dilutive.

12. 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 September 30,		Nine Months Ended September 30,	
(U.S. Dollars, in thousands)	**2014**	**2013**	**2014**	**2013**
Cost of sales	$ 40	$ 27	$ 98	$ (249)
Sales and marketing	537	469	1,410	1,375
General and administrative	1,069	726	2,368	3,431
Research and development	84	55	227	157
Total	$ 1,730	$ 1,277	$ 4,103	$ 4,714

On June 30, 2014, the Company granted restricted share awards to executive employees, which vesting is based on achieving earnings targets in two consecutive rolling four quarter periods. In March 2013, the Company granted options to its newly-appointed Chief Executive Officer, which vesting is based on achieving certain market prices for the Company s common stock.

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During the three and nine months ended September 30, 2014, there were 69,572 and 501,862 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the three and nine months ended September 30, 2013, there were 56,281 and 199,725 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

13. Income taxes

The Company recognized a $9.3 million and $8.0 million provision for income tax which reflects an effective tax rate of 87.3% and (1,397.3)% on pre-tax income for the nine months ended September 30, 2014, and 2013, respectively. Excluding the impact of various discrete charges, the effective tax rate on continuing operations for the first nine months of 2014 and 2013 was 68.4% and (1,422.4.)%, respectively. The principal factors affecting the Company s September 30, 2014, 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 resulting from non-recurring expenses.

As of September 30, 2014 and December 31, 2013, the Company s unrecognized tax benefit was $0.7 million. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits in income tax expense. The Company had approximately $0.5 million accrued for payment of interest and penalties as of September 30, 2014, and December 31, 2013. The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company s effective tax rate if recognized. 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.

14. Business segment information

The Company manages the business by 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 the Chief Executive Officer, who is also our Chief Operating Decision Maker (CODM), reviews financial information and makes resource allocation decisions among business units. The primary metric used by the CODM 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, segment information has been prepared based on four SBUs reporting segments. These four segments are discussed below.

BioStim

The BioStim SBU manufactures, distributes, and provides support services for 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 the cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). The devices utilize Orthofix s patented pulsed electromagnetic field (PEMF) technology which is supported by strong basic mechanism of action data in the scientific literature 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.

Biologics

Biologics provides a portfolio of regenerative products that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This SBU specializes in the marketing of regeneration tissue forms. Biologics markets its tissues through a network of distributors, sales representatives and affiliates to supply to hospitals, doctors, and other healthcare providers, primarily in the U.S. The Company s partnership with Musculoskeletal Transplant Foundation (MTF) allows the Company to exclusively market Trinity Evolution® and Trinity ELITE® tissue forms for musculoskeletal defects to enhance bony fusion as well as VersaShield for which we have non-exclusive rights.

Extremity Fixation

The Extremity Fixation SBU offers products 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. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates. This SBU uses both direct and distributor sales representatives to sell orthopedics products to hospitals, doctors, and other health providers, globally.

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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 distributor sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.

Corporate

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

The accounting policies of the segments are the same as those described in the business segment information found in Note 13, Business segment information to the Consolidated Financial Statements included in the 2013 Form 10-K/A.

The table below presents external net sales by SBU reporting segment (amounts reported for prior periods have been reclassified to conform to the new segment reporting structure). Net sales include product sales and marketing service fees. Marketing service fees, which are recorded on a net basis, are comprised of fees earned for the marketing of Trinity Evolution®, Trinity ELITE® and Versashield in the Biologics segment.

	External Net Sales by SBU Three Months Ended September 30,			
(U.S. Dollars, in thousands)	**2014**	**2013 (Restated)**	**Reported Growth**	**Constant Currency Growth**
BioStim	$ 38,285	$ 30,654	25%	25%
Biologics	13,856	13,216	5%	5%
Extremity Fixation	27,636	24,705	12%	9%
Spine Fixation	21,217	23,231	(9)%	(9)%
Total Net Sales	$ 100,994	$ 91,806	10%	9%

	External Net Sales by SBU Nine Months Ended September 30,			
(U.S. Dollars, in thousands)	**2014**	**2013 (Restated)**	**Reported Growth**	**Constant Currency Growth**
BioStim	$ 114,937	$ 105,828	9%	9%
Biologics	40,718	39,816	2%	2%
Extremity Fixation	82,005	74,112	11%	9%
Spine Fixation	64,333	71,969	(11)%	(11)%

Total Net Sales	$ 301,993	$ 291,725	4%	3%

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The table below presents net margin, defined as gross profit less sales and marketing expenses, from continuing operations by SBU reporting segment:

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013 (Restated)	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013 (Restated)
Net margin:				
BioStim	$ 16,442	$ 13,397	$ 49,168	$ 48,614
Biologics	6,504	6,737	19,500	18,463
Extremity Fixation	8,361	7,089	21,952	17,980
Spine Fixation	3,958	913	11,147	5,796
Corporate	(537)	(470)	(1,411)	(1,376)
Total net margin	34,728	27,666	100,356	89,477
General and administrative	18,814	12,933	53,643	46,355
Research and development	6,572	6,361	18,818	20,653
Amortization of intangible assets	508	616	1,753	1,725
Costs related to the accounting review and restatement	2,326	2,664	12,959	2,664
Impairment of goodwill		19,193		19,193
Operating income	$ 6,508	$ (14,101)	$ 13,183	$ (1,113)

15. Sale of Breg

In May of 2012, the Company sold its subsidiary Breg, Inc. In connection with this sale transaction, the Company agreed to indemnify the buyer with respect to certain specified matters. The portion of the indemnification related to post closing claims related to post-closing sales of cold therapy units has created a guarantee under Accounting Standards Codification *ASC 460, Guarantees*, and the fair value of the liability has been recorded under the initial recognition criteria in the amount of $2 million at the closing date. The Company is amortizing the fair value of the non-contingent liability ratably over the period of indemnification, which is three years. The Company s remaining obligations under this guarantee were approximately $0.4 million and $0.9 million as of September 30, 2014 and December 31, 2013, respectively.

Discontinued operations for the three and nine months ended September 30, 2014 is $0.2 million and $5.0 million, respectively, of expense related to the Company s indemnification of certain specified matters described above.

16. Contingencies

The Company is party to certain outstanding legal proceedings, investigations and claims. These matters are described in the 2013 Form 10-K/A. As of the end of the period covered by this report, there had been no further material developments with respect to these matters other than as described below.

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As previously disclosed, at the time of its divestiture by the Company in 2012, the Company s sports medicine subsidiary, Breg, Inc., 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 were filed in recent years, mostly in California state court, alleging that 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. In connection with the Company s divestiture of Breg, the Company agreed to indemnify Breg s acquirer for Breg s pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. In September 2014, the Company entered into a master settlement agreement that resolves the pending claims with respect to all except one claim pending in a California coordinated proceeding concerning pre-closing sales. 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 have been recorded as an expense during the fiscal quarter ended June 30, 2014.

In addition, the Company does not accrue for estimated legal fees and other directly related costs as they are expensed as incurred.

17. Stock repurchase program

On May 8, 2013, the Company announced that its Board of Directors had authorized a share repurchase program in an amount up to $50 million. To date, the Company has made total repurchases in an amount equal to $39.5 million, all of which were made between May and July 2013.

18. Subsequent events

On August 14, 2014 the Lenders and the Company entered into a subsequent Limited Waiver which was extended on September 30, 2014, January 15, 2015 and February 26, 2015 (the Subsequent Limited Waivers). Under the Subsequent Limited Waivers, the Lenders collectively waived requirements under the Credit Agreement that the Company deliver quarterly financial statements with respect to the fiscal quarters ended June 30, 2014 and September 30, 2014, and related financial covenant certificates, until the earlier of (i) March 31, 2015 or (ii) the date that is one day after such financial statements are publicly filed or released. The Subsequent Limited Waivers also extend the date by which the Company is required to provide certain 2014 fiscal year financial statements until the earlier of (i) one business day following the date that the Company files its Annual Report on Form 10-K for the fiscal year ended December 31, 2014 or (ii) April 30, 2015. In addition, the Subsequent Limited Waivers provided that the Further Restatement would not constitute a default or event of default provided that within one business day after the public release or filing of such restated financial statements, the Company delivered corrected financial statements and compliance certificates with respect to such restated periods and immediately paid any additional interest and other fees that would have been owed had applicable interest and fees originally been calculated based on the restated financial statements.

In January 2015, the Company completed the sale of its Tempus Cervical Plate product line, which was part of the Company s Spine Fixation SBU. The sale included the transfer of net assets of $2.1 million, consisting of intellectual property and the associated inventory, in exchange for consideration of $4.8 million in cash.

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 $250,000 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 $15,000,000 and interest will accrue at 8%. The eNeura Note will mature on the earlier of (i) March 4, 2019, or (ii) consummation of the acquisition (as described below), unless converted or prepaid at an earlier date. The Company will be entitled to designate one representative for appointment to the board of directors of eNeura during the 18-month option period. Pursuant to an Agreement and Plan of Merger between the Company, eNeura and certain other parties, if the Company exercises the Option to acquire eNeura, the Company will pay to former eNeura shareholders $65 million (subject to certain positive or negative adjustments based on the assets and liabilities of eNeura). In addition, during the 4-year period following the closing of such acquisition, the Company may be required to pay additional cash consideration to eNeura shareholders upon the satisfaction of certain milestones.

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

As further described in the explanatory note to this Report, as well as in Note 2 to the consolidated financial statements included in Part I, Item 1 herein, the Company has restated its previously issued consolidated financial statements for certain prior periods, including the fiscal quarter ended September 30, 2013. The Company refers to such restatement as the Further Restatement. Accordingly, this Management s Discussion and Analysis of Financial Condition and Results of Operations has been revised to reflect the effects of the Further Restatement.

The following discussion and analysis addresses the results of operations which are based upon the condensed consolidated financial statements included herein, which have been prepared in accordance with U.S. GAAP, for the three and nine months ended September 30, 2014, compared to the three and nine months ended September 30, 2013. These discussions should be read in conjunction with historical consolidated financial statements and related notes thereto and the other financial information included in this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 (this Report).

Business Segments

Segment information is prepared on the same basis that management reviews the financial information for operational decision making purposes. The Company manages the business by 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 the 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, segment information has been prepared based on four SBUs reporting segments. These four segments are discussed below.

BioStim

The BioStim SBU manufactures, distributes, and provides support services for 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 the cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). The devices utilize Orthofix s patented pulsed electromagnetic field (PEMF) technology which is supported by strong basic mechanism of action data in the scientific literature 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.

Biologics

Biologics provides a portfolio of regenerative products that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This SBU specializes in the marketing of regeneration tissue forms. Biologics markets its tissues through a network of distributors, sales representatives and affiliates to supply to hospitals, doctors, and other healthcare providers, primarily in the U.S. The Company s partnership with Musculoskeletal Transplant Foundation (MTF) allows the Company to exclusively market Trinity Evolution® and Trinity ELITE® tissue forms for musculoskeletal defects to enhance bony fusion as well as VersaShield for which we have non-exclusive rights.

Extremity Fixation

The Extremity Fixation SBU offers products 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. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates. This SBU uses both direct and distributor sales representatives to sell orthopedics 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 distributor 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.

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SBU Revenues

The table below presents external net sales for the three and nine months ended September 30, 2014 and 2013, from continuing operations, by SBU reporting segment (amounts reported for prior periods have been reclassified to conform to the new segment reporting structure):

	External Net Sales by SBU Three Months Ended September 30,			
(U.S. Dollars, in thousands)	**2014**	**2013 (Restated)**	**Reported Growth**	**Constant Currency Growth**
BioStim	$ 38,285	$ 30,654	25%	25%
Biologics	13,856	13,216	5%	5%
Extremity Fixation	27,636	24,705	12%	9%
Spine Fixation	21,217	23,231	(9)%	(9)%
Total Net Sales	$ 100,994	$ 91,806	10%	9%

	External Net Sales by SBU Nine Months Ended September 30,			
(U.S. Dollars, in thousands)	**2014**	**2013 (Restated)**	**Reported Growth**	**Constant Currency Growth**
BioStim	$ 114,937	$ 105,828	9%	9%
Biologics	40,718	39,816	2%	2%
Extremity Fixation	82,005	74,112	11%	9%
Spine Fixation	64,333	71,969	(11)%	(11)%
Total Net Sales	$ 301,993	$ 291,725	4%	3%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014 (%)	**2013 (%) (Restated)**	**2014 (%)**	**2013 (%) (Restated)**
Net sales	100	100	100	100
Cost of sales	25	27	26	25

Gross profit	75	73	74	75
Operating expenses:				
Sales and marketing	40	42	41	44
General and administrative	19	14	18	16
Research and development	7	7	6	7
Amortization of intangible assets	1	1	1	1
Costs related to the accounting review and restatement	2	3	4	1
Impairment of goodwill		21		7
Operating income (loss)	6	(15)	4	(1)
Net income (loss)	1	(21)	(1)	(6)

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Three Months Ended September 30, 2014 Compared to Three Months Ended September 30, 2013

Total Net Sales The increase in Net Sales of $9.2 million to $101.0 million in the third quarter of 2014 compared to $91.8 million for the same period last year is driven by sales increases in three of the four SBU s: BioStim, Biologics, and Extremity Fixation, with details of the increases provided below. Favorable changes in foreign currency increased sales by $0.7 million during the third quarter of 2014 relative to the same period in 2013.

Sales

Net sales in the BioStim SBU increased 24.8% to $38.3 million in the third quarter of 2014 compared to $30.7 million for the same period in the prior year, an increase of $7.6 million. The increase was primarily due to the reduction in third party payor revenue driven by our transition during the third quarter of 2013 to recognize revenue upon accumulation of the full billable package for third party payors, and to a lesser extent, volume growth due to enhancements to the BioStim sales organization.

Net sales in the Biologics SBU increased $0.7 million or 5.3% to $13.9 million in the third quarter of 2014 compared to $13.2 million for the same period in the prior year. The growth is primarily driven by an expanded sales channel as well as continued conversion to our next generation cell-based bone growth tissue technology (Trinity ELITE®).

Net sales in the Extremity Fixation SBU increased $2.9 million or 11.7%, to $27.6 million in the third quarter of 2014 compared to $24.7 million for the same period last year. The growth is driven by recent expanded product launches and improvement in international sales partially offset by declining revenue in Brazil which has experienced significant disruption to the sales channel over the past year as we rebuild our sales organization.

Net sales in the Spine Fixation SBU decreased $2.0 million or 8.6% to $21.2 million in the third quarter of 2014 compared to $23.2 million for the same period last year primarily due to loss of sales momentum resulting from our efforts to reorganize the sales force in late 2013 as well as the first and second quarter of 2014 to improve profitability.

Gross Profit Gross profit increased $9.0 million to $75.7 million in the third quarter of 2014 compared to $66.7 million for the same period last year. Gross profit as a percent of net sales was 75.0% for the third quarter of 2014 and 72.7% for 2013 during the same period. This increase is primarily driven by the change in third party payor revenue for the BioStim business which recognized revenue upon accumulation of the full billable package for third party payors causing third quarter 2013 revenue to be lower due to revenue recognition timing. In addition, third quarter of 2013 included additional reserve for excess and obsolete products in multiple SBUs.

Sales and Marketing Expense Third quarter 2014 sales and marketing expense was $41.0 million or 40.6% of net sales compared to $39.1 million or 42.6% of net sales in same period prior year, and includes commissions and the provision for bad debt. Sales expenses for the third quarter of 2014 increased compared to prior year due primarily to higher commissions resulting from the increased BioStim sales.

General and Administrative Expense General and administrative expense increased $5.9 million, or 45.7%, in the third quarter of 2014 to $18.8 million compared to $12.9 million in the third quarter of 2013. General and administrative expense as a percent of net sales was 18.6% in the third quarter of 2014, compared to 14.1% for the same period last year. The increase in G&A is primarily driven by investment in the following improvements: implementation of an internal audit function; focused efforts on key process improvements; and remediation of material weaknesses and significant deficiencies. Further $1.5 million was spent during the third quarter of 2014 on our multi-year process and systems improvement effort, Bluecore.

Research and Development Expense Research and development expense increased $0.2 million in the third quarter of 2014 to $6.6 million compared to $6.4 million in the same period prior year. Research and development expense as a percent of net sales was 6.5% in the third quarter of 2014, compared to 6.9% for the same period last year as a result of increased spending in both clinical and pre-clinical studies.

Amortization of Intangible Assets Amortization of intangible assets decreased slightly to $0.5 million in the third quarter of 2014 from $0.6 million for the same period in 2013 due to the complete amortization of Italian assets.

Costs related to the accounting review and restatement As part of our accounting review and restatement of our consolidated financial statements, the Company incurred $2.3 million of charges related to these activities in the third quarter of 2014 compared to $2.7 million for the same period last year. There will continue to be fees related to restatement activities through the rest of 2014.

Impairment of Goodwill As part of our change in reportable segments in the third quarter of 2013, we reallocated goodwill to each new reporting unit, and subsequently evaluated each reporting unit for impairment. As a result of this analysis, a full impairment of the goodwill allocated to our Spine Fixation and Extremity Fixation reporting units, of $19.2 million, was recognized.

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Interest Expense, net Net interest expense decreased slightly to $0.4 million for the third quarter of 2014 compared to $0.5 million for the same period a year ago as there were limited changes to our long-term debt obligations until late in the third quarter of 2014, when the outstanding revolver balance was paid down.

Other Income and Expense Other expense was $1.3 million compared to other expense of $1.5 million for the third quarters of 2014 and 2013, respectively. Other income and expense includes the effect of foreign currency transactions. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) currency.

Income Tax Expense Our worldwide effective tax rate was 99.4% and (2.4)% during the third quarters of 2014 and 2013, respectively. Excluding the impact of various discrete charges, the effective tax rate for the second quarter of 2014 and 2013 was 74.7% and (3.4)% respectively. The principal factors affecting the Company s third quarter 2014, 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 resulting from non-recurring expenses.

Discontinued operations Discontinued operations include a benefit of approximately $0.4 million and a loss of approximately $2.3 million in the third quarter of 2014 and 2013, respectively, from legal settlements and legal costs, net of income taxes, which relate to certain specified product liability matters in relation to the Company s former subsidiary, Breg. The Company agreed to indemnify Breg and its purchaser with respect to such matters. The legal fees related to Breg should cease over time.

Net Income (loss) Net income for the third quarter of 2014 was $0.5 million, or $0.02 per basic and diluted share, compared to net loss of $18.8 million, or $1.04 per basic share and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 18,577,540 and 18,142,935 during the three months ended September 30, 2014 and 2013, respectively. The weighted average number of diluted common shares outstanding was 18,809,554 and 18,142,935 during the three months ended September 30, 2014, and 2013, respectively.

Nine Months Ended September 30, 2014 Compared to Nine Months Ended September 30, 2013

Total Net Sales Net sales increased $10.2 million to $301.9 million in the first nine months of 2014 compared to $291.7 million for the same period last year. The impact of changes in foreign currency increased sales by $1.3 million during the first nine months of 2014 relative to first nine months of 2013. The Extremity Fixation SBU experienced an 11% increase in sales during the first nine months of 2014 relative to the same period in 2013. BioStim and Biologics also experienced a growth in sales of 9% and 2% over the prior year, while Spine Fixation sales have declined by 11% during the first nine months of 2014 compared to the same period last year.

Sales

Net sales in the BioStim SBU increased 8.6% to $114.9 million in the first nine months of 2014 compared to $105.8 million for the same period in the prior year, an increase of $9.1 million. This year-over-year increase was primarily due to the reduction in third party payor revenue driven by our billable package transition in the third quarter of 2013, and to a lesser extent, order volume growth as a result of enhancements to the BioStim sales organization.

Net sales in the Biologics SBU increased $0.9 million to $40.7 million in the first nine months of 2014 compared to $39.8 million for the same period in the prior year due to an expanded sales channel as well as continued conversion to our next generation cell-based bone growth tissue technology (Trinity ELITE®). These increases were offset

slightly by a reduction in marketing fees received from Musculoskeletal Transplant Foundation (MTF) for Trinity products from 70% of retail price to 65% starting in April 2013.

Net sales in the Extremity Fixation SBU increased $7.9 million, to $82.0 million in the first nine months of 2014 compared to $74.1 million for the same period last year. Year-over-year revenue comparisons are impacted by the transition to sell-through accounting for certain of the Company s distributors in the second quarter of 2013. Recent expanded product launches have also contributed to increased sales as well as increased sales in the U.S. for our TrueLok product line. These items are partially offset by declining revenue in Brazil which has experienced significant disruption to the sales channel over the past year as we rebuild our Brazil sales organization.

Net sales in the Spine Fixation SBU decreased $7.7 million or 10.4% to $64.3 million in the first nine months of 2014 compared to $72.0 million for the same period last year primarily due to loss of sales momentum resulting from our efforts to reorganize the sales force in late 2013 as well as the first and second quarter of 2014 to improve profitability.

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Gross Profit Gross profit increased $5.6 million to $224.5 million in the first nine months of 2014 compared to $218.9 million for the same period last year. Gross profit as a percent of net sales was 74.4% for the first nine months of 2014 and 75.0% for 2013 during the same period. The decrease in gross margin is primarily driven by changes in product and sales channel mix from rebuilding of our Brazil sales organization and reserves for excess and obsolete products across multiple SBUs.

Sales and Marketing Expense Sales and marketing expense, which includes variable expenses such as commissions and the bad debt provision, decreased 4.1% for the first nine months of 2014 compared to prior year. However, tighter cost controls on non-variable sales and marketing expenses, lower commission rates due to the reorganization of the Brazil sales force, as well as lower Spine sales, resulted in an overall decrease in expense of $5.3 million down to $124.2 million compared to $129.5 million for the same period in the prior year. As a percent of net sales, sales and marketing related expense was 41.1% compared to 44.4% for the same period last year.

General and Administrative Expense General and administrative expense increased $7.2 million, or 15.5%, in the first nine months of 2014 to $53.6 million compared to $46.4 million in the first nine months of 2013. General and administrative expense as a percent of net sales was 17.8% for the first nine months of 2014, compared to 15.9% for the same period last year. This increase is primarily driven by investment in the following improvements: implementation of an internal audit function; focused efforts on key process improvements; and remediation of material weaknesses and significant deficiencies. Additionally, as the Company is self insured up to a loss threshold, unusually high medical insurance payouts in 2014 as compared to 2013, further exacerbated the increase in general and administrative expense. Approximately, $1.5 million has been spent year-to-date on our multi-year process and systems improvement effort, Bluecore.

Research and Development Expense Research and development expense decreased $1.9 million in the first nine months of 2014 to $18.8 million compared to $20.7 million in the first nine months of 2013. As a percent of net sales, research and development expense was 6.3% in the first nine months of 2014 compared to 7.1% for the same period last year. The decrease was primarily driven by a $2 million payment to Musculoskeletal Transplant Foundation (MTF) in the second quarter of 2013 for the development and commercialization of Trinity ELITE, which was released in the first half of 2013.

Amortization of Intangible Assets Amortization of intangible assets increased slightly to $1.8 million for the first nine months of 2014 compared to $1.7 million for the same period last year due to the amortization of milestone payments associated with licensing new products in the second half of 2013.

Costs related to the accounting review and restatement As part of our accounting review and restatement of our consolidated financial statements, the Company incurred $13.0 million of charges related to these activities in the first nine months of 2014 compared to $2.7 million in the same period last year. There will continue to be fees related to restatement activities in 2014.

Impairment of Goodwill As part of our change in reportable segments in the third quarter of 2013, we reallocated goodwill to each new reporting unit, and subsequently evaluated each reporting unit for impairment. As a result of this analysis, a full impairment of the goodwill allocated to our Spine Fixation and Extremity Fixation reporting units, of $19.2 million, was recognized.

Interest Expense, net Net interest expense decreased $0.1 million to $1.4 million for the first nine months of 2014 compared to $1.5 million the same period a year ago as there was limited changes to our long-term debt borrowings until late in the third quarter of 2014, when the outstanding revolver balance was paid down.

Other Income and Expense Other expense was $1.2 million compared to other income of $2.1 million for the first nine months of 2014 and 2013, respectively. The fluctuation is mainly attributable to our receipt of $4.4 million cash in the first quarter of 2013 related to the demutualization of a mutual insurance company in which we were an eligible member to share in such proceeds. Other income (expense) also includes the effect of foreign exchange transactions. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional currency which results in foreign exchange gains or losses when there is relative movement between those currencies.

Income Tax Expense Our worldwide effective tax rate was 87.3% and (1,397.3)% during the first nine months of 2014 and 2013, respectively. Excluding the impact of various discrete charges, the effective tax rate on continuing operations for the first nine months of 2014 and 2013 was 68.4% and (1,422.4)%, respectively. The principal factors affecting the Company s nine months September 30, 2014, 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 resulting from non-recurring expenses.

Discontinued operations Discontinued operations include losses of approximately $4.1 million and $9.8 million in the first nine months of 2014 and 2013, respectively, from legal settlements and legal costs, net of income taxes, which relate to certain specified product liability matters in relation to the Company s former subsidiary, Breg. Orthofix agreed to indemnify Breg and its purchaser with respect to such matters.

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Net loss Net loss for the first nine months of 2014 was $2.7 million, or $0.15 per basic and diluted share, compared to net loss of $18.4 million, or $0.97 per basic share and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 18,408,238 and 18,897,887 during the nine months ended September 30, 2014 and 2013, respectively. The weighted average number of diluted common shares outstanding was 18,408,238 and 18,897,887 during the nine months ended September 30, 2014, and 2013, respectively.

Liquidity and Capital Resources

Cash and cash equivalents including restricted cash at September 30, 2014, were $64.5 million, of which $34.6 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of $52.7 million at December 31, 2013, of which $23.8 million was subject to certain restrictions under the senior secured credit agreement discussed below.

Net cash provided by operating activities was $36.0 million and $51.9 million, respectively, for the nine months ended September 30, 2014, and 2013, respectively. Net cash used by and provided by operating activities is comprised of net income, adjusted for 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 decreased $15.7 million to a net loss of $2.7 million for the nine months ended September 30, 2014, from net loss of $18.4 million for the comparable period in the prior year. Non-cash items for the nine months ended September 30, 2014, decreased $17.0 million to $25.4 million compared to non-cash items of $42.4 million in the same period of 2013, 2013 included $19.2 million impairment of goodwill. Working capital accounts provided $13.3 million of cash for the nine months ended September 30, 2014, compared to $27.9 million for the nine months ended September 30, 2013. Overall performance indicators for the Company s two primary working capital accounts, accounts receivable and inventory reflect day s sales in receivables of 56 days at September 30, 2014, and 71 days at September 30, 2013, and inventory turns of 1.7 times as of September 30, 2014, and 1.2 times as of September 30, 2013. The decrease in day s sales in receivables is due primarily to a continual improvement in collections of receivables from international distributors, as well as a transition to sell-through accounting for certain of the Company s distributors in the second quarter of 2013 in Extremity Fixation, resulting in a continual decrease in receivables, while the increase in inventory turns is due to increased efficiency in inventory management resulting in a decrease in inventory.

Net cash used by investing activities was $12.9 million for the nine months ended September 30, 2014, compared to $25.2 million for the nine months ended September 30, 2013. The decrease in cash used by investing activities of $12.5 million is due primarily to a decrease in investment in surgical instruments as well as license and distribution agreements for the Company s products.

Net cash used in financing activities was $20.5 million for the nine months ended September 30, 2014, compared to $37.4 million for the same period in 2013. During the nine months ended September 30, 2014 the company paid down $20.0 million of long term debt. In the same period in 2013, the Company made no repayments on revolving debt. Our restricted cash balance increased to $34.6 million due to a cash use of $11.0 million in the nine months ended September 30, 2014, compared to cash use of $1.4 million, in the nine months ended September 30, 2013, primarily related to the cash received from the Blackstone escrow fund which was recorded in Restricted Cash in accordance with the credit facility. During the nine months ended September 30, 2014 the Company received proceeds of $10.3 million, respectively, from the issuance of 501,862 shares compared to the repurchase of 1,437,758 shares for a total of $39.5 million, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

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 of the Company s domestic direct and

indirect subsidiaries (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 provides 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 September 30, 2014, the Term Loan Facility has been repaid in full and there was no outstanding balance under the Revolving Credit Facility. Borrowings under the Credit Facilities bear interest at a floating rate, which is, at Orthofix Holdings option, either the London Inter-Bank Offered Rate (LIBOR) plus an applicable margin or a base rate (as defined in the Credit Agreement) plus an applicable margin (in each case subject to adjustment based on financial ratios). Such applicable margin will be up to 3.25% for LIBOR borrowings and up to 2.25% for base rate borrowings depending upon a measurement of the consolidated

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leverage ratio with respect to the immediately preceding four fiscal quarters. As of September 30, 2014, and December 31, 2013, the entire Revolving Credit Facility was at the LIBOR rate plus a margin of 2.50%. The effective interest rate on the Credit Facilities at September 30, 2014 and December 31, 2013 was 2.70%.

Outstanding balances on the Revolving Credit Facility are due on August 30, 2015.

Borrowings under the Revolving Credit Facility, which may be made in the future, may be used for working capital, capital expenditures and other general corporate purposes of Orthofix Holdings and its subsidiaries. The Guarantors have guaranteed repayment of Orthofix Holdings obligations under the Credit Agreement. The obligations of Orthofix Holdings and each of the Guarantors with respect to the Credit Facilities are secured by a pledge of substantially all of the assets of Orthofix Holdings and each of the Guarantors.

The Credit Agreement, as amended, requires the Company and Orthofix Holdings to comply with coverage ratios on a consolidated basis and contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. On August 14, 2013, the Company entered into a Limited Waiver (the Original Limited Waiver) with the lenders under the Credit Agreement (the Lenders) which waived requirements under the Credit Agreement to deliver quarterly financial statements for the fiscal quarter ended on June 30, 2013, and related financial covenant certificates, until the earlier of (i) March 31, 2014 or (ii) the date that is one day after such financial statements are publicly filed or released. The Company was in compliance with the affirmative and negative covenants as of September 30, 2014, and there were no events of default.

In connection with the Further Restatement and the Company s delay in filing this Report, on August 14, 2014 the Company entered into a subsequent Limited Waiver with the Lenders, which was extended on September 30, 2014, January 15, 2015 and February 26, 2015 (the Subsequent Limited Waivers). Under the Subsequent Limited Waivers, the Lenders collectively waived requirements under the Credit Agreement that the Company deliver quarterly financial statements with respect to the fiscal quarters ended June 30, 2014 and September 30, 2014, and related financial covenant certificates, until the earlier of (i) March 31, 2015 or (ii) the date that is one day after such financial statements are publicly filed or released. The Subsequent Limited Waivers also extend the date by which the Company is required to provide certain 2014 fiscal year financial statements until the earlier of (i) one business day following the date that the Company files its Annual Report on Form 10-K for the fiscal year ended December 31, 2014 or (ii) April 30, 2015. In addition, the Subsequent Limited Waivers provided that the Further Restatement would not constitute a default or event of default provided that within one business day after the public release or filing of such restated financial statements, the Company delivered corrected financial statements and compliance certificates with respect to such restated periods and immediately paid any additional interest and other fees that would have been owed had applicable interest and fees originally been calculated based on the restated financial statements. As of the date hereof, the Company has delivered the quarterly consolidated financial statements for the fiscal quarters ended June 30, 2014 and September 30, 2014, and the Company does not expect the Further Restatement to trigger any such additional interest or fees with respect to such prior periods. However, in the event that the Company does not satisfy these respective obligations under the Subsequent Limited Waivers and/or the Credit Agreement, an event of default could be declared under the Credit Agreement, which could have a material adverse effect on the Company s financial position.

Certain of the Company s subsidiaries have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. The Company s domestic subsidiaries, as parties to the Credit Agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of September 30, 2014, and December 31, 2013, was $178.3 million and $168.5 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities

from access to cash held by Orthofix Holdings and its subsidiaries. The amount of restricted cash as of September 30, 2014, and December 31, 2013, was $34.6 million and $23.8 million, respectively.

At September 30, 2014, there were no outstanding bank borrowings and an unused available line of credit of approximately 5.8 million ($7.3 million) under the line of credit established in Italy to finance the working capital of the Company s Italian operations. The terms of the line of credit give the Company the option to borrow amounts in Italy at rates determined at the time of borrowing.

On May 8, 2013, the Company announced that its Board of Directors had authorized a share repurchase program in an amount up to $50 million. Repurchases began on May 10, 2013, consisting primarily of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Securities Exchange Act of 1934, as amended. Repurchases are being made from cash on hand, cash generated from operations and additional borrowings. The timing of the transactions and the aggregate number of shares of common stock that will be ultimately repurchased under the repurchase program will depend on a variety of factors, including market conditions and the prices at which the securities are repurchased. The Company may discontinue repurchases without prior notice at any time if the Company determines additional repurchases are not warranted. During the fiscal quarter ended September 30, 2014, the Company made no repurchases. The Company has not made any further purchases between September 30, 2014, and the date hereof. To date, the Company has made total repurchases in an amount equal to $39.5 million.

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The Company believes that current cash balances together with projected cash flows from operating activities, the availability of $200 million under the revolving credit facility, the available Italian line of credit and the Company s debt capacity are sufficient to cover additional stock repurchases, anticipated working capital and capital expenditure needs including research and development costs over the next twelve months.

The Company s intention is to reinvest the total amount of its unremitted foreign earnings (residing outside Curaçao) in the local jurisdiction, to the extent they are generated and available, or to repatriate the earnings only when tax-effective. As an entity incorporated in Curaçao, foreign subsidiaries refer to both U.S. and non-U.S. subsidiaries. Furthermore, only income sourced in the U.S. is subject to U.S. income tax. It is not practicable to determine the amounts of net additional income tax that may be payable if such earnings were repatriated. The Company does not anticipate any impact on income tax liabilities since earnings are permanently reinvested for both U.S. and non-U.S. subsidiaries.

Contractual Obligations

There have been no material changes in any of our contractual obligations as disclosed in our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2013, filed on March 30, 2015, except for the Revolving Credit Facility that has been repaid in full during the third quarter of 2014.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company is exposed to certain market risks as part of ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations, cost of financing and yields on cash and short-term investments. The Company uses derivative financial instruments, where appropriate, to manage these risks. However, the risk management policy does not allow the Company to hedge positions not held, or enter into derivative or other financial investments for trading or speculative purposes. As of September 30, 2014, a currency swap was in place to minimize foreign currency exchange risk related to a 28.7 million ($36.3 million translated at the September 30, 2014, foreign exchange rate) intercompany note. As of September 30, 2014, the fair value of the currency swap was approximately $1.8 million and is recorded in other long-term receivables.

The Company is exposed to interest rate risk in connection with the Term Loan Facility and Revolving Credit Facility, which bear interest at floating rates based on LIBOR plus an applicable borrowing margin or at a base rate (as defined in the Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant.

As of September 30, 2014, borrowings under the Revolving Credit Facility are borrowed at the LIBOR rate plus a margin of 2.50%. The margin is adjusted based upon the measurement of the consolidated leverage ratio of the Company and the Company s subsidiaries with respect to the immediately preceding four fiscal quarters. As of September 30, 2014, the effective interest rate on the Credit Facilities was 2.70%. As of September 30, 2014, there was no balance outstanding under the Credit Facilities, and an immediate change of one percentage point in the applicable interest rate on the Revolving Credit Facility would not have an effect on interest expense.

The Company s foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Great Britain Pound, Mexican Peso and Brazilian Real. The Company is subject to cost of sales currency exposure when the Company produces products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. The Company is subject to transactional currency exposures when

foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. As of September 30, 2014, the Company had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million ($29.3 million). The Company recorded a foreign currency loss during the three and nine months ended September 30, 2014, of $2.5 and $2.6 million, respectively, related to this un-hedged long-term intercompany note in accumulated other comprehensive income, which resulted from the strengthening of the U.S. dollar against the Euro during the period. For the three and nine months ended September 30, 2014, the Company recorded a foreign currency loss of ($0.2) million and a gain of $0.2 million, respectively, on the statement of operations resulting from gains and losses in foreign currency transactions.

The Company is also subject to currency exposure from translating the results of global operations into the U.S. dollar at exchange rates that have fluctuated during the period. As the Company continues to distribute and manufacture products in selected foreign countries, the Company expect that future sales and costs associated with activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact operating results.

Item 4. Controls and Procedures

Background of Restatements

Original Restatement

In July 2013, members of the Company s senior management brought certain information to the attention of the chair of the Audit Committee (Audit Committee) of the Company s Board of Directors (the Board) that raised questions regarding whether the Company had properly recognized revenue under U.S. GAAP in connection with revenue from distributor sales that had been

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recorded in 2012 and 2011, including a significant return processed in the second quarter of 2013 relating to revenue recognized in 2012. On the recommendation of management and after discussion with the Company s independent registered public accounting firm, Ernst & Young LLP (Ernst & Young), the Audit Committee concluded, with the concurrence of the Board, that it would commence an independent review into these matters with the assistance of outside professionals engaged by the Audit Committee (the Independent Review).

On August 5, 2013, the Audit Committee concluded that certain revenues recognized during 2012 and 2011, upon further evaluation, should not have been recognized or should not have been recognized during the periods in which they were recognized. As a result of the foregoing, on August 5, 2013, the Audit Committee concluded that the Company s previously issued consolidated financial statements as of and for the fiscal years ended December 31, 2012 and December 31, 2011, as well as for the interim quarterly period ended March 31, 2013, should no longer be relied upon (the Non-Reliance Period). On August 6, 2013, the Board ratified the foregoing conclusion by the Audit Committee.

The Independent Review focused on the periods between January 1, 2010 and March 31, 2013 and included (i) over 50 witness interviews, (ii) collection of emails and files from 70 document custodians, and (iii) quantitative analysis. The scope of the Independent Review, which was determined by the Audit Committee in consultation with outside professionals engaged by the Audit Committee, focused primarily on revenue recognition related to distributor arrangements and inventory reserve adjustments. In conjunction with the Independent Review, management concluded that errors existed in the Company s previously issued financial statements with respect to the Non-Reliance Period, as well as in the Company s previously issued consolidated financial statements for the fiscal years ended December 31, 2010, 2009, 2008 and 2007. The error corrections related to the foregoing, which we refer to herein as the Original Restatement, were contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2013 file on March 31, 2014 (Original 2013 Form 10-K).

In reaching the error correction conclusions that were reflected in the Original Restatement, the Company considered information obtained in the Independent Review, including emails, data and interviews with current and former employees that indicated (i) the existence of extra-contractual terms or arrangements at the onset of the sale and concessions agreed to subsequent to the initial sale (such as extended payment terms and return and exchange rights for sales to distributors with respect to certain transactions), including some with which certain senior-level personnel were involved, (ii) that at the time of some sales collection was not reasonably assured, and (iii) that certain amounts previously characterized as commissions were paid to related parties of the applicable customer.

The Company assessed the information derived from the Independent Review in making determinations with respect to accounting adjustments reflected in the restated consolidated financial statements contained in Original 2013 Form 10-K, and such determinations were consistent with the findings of the Independent Review. In addition to the matters that were the subject of the Independent Review, certain other adjustments identified by management, including revisions to inventory reserves and royalties, were made to the consolidated financial statements in connection with the restatement.

Further Restatement

In connection with the Company s preparation of its consolidated interim quarterly financial statements for the fiscal quarter ended June 30, 2014, the Company determined that certain manual journal entries with respect to the previously filed consolidated financial statements contained in the Original 2013 Form 10-K and the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2014 (the Original 2014 First Quarter Form 10-Q) were not properly accounted for under U.S. GAAP. As further described below, these additional errors affect the fiscal years ended December 31, 2013, 2012 and 2011, as well as the fiscal quarter ended March 31, 2014 and

other prior periods. Due to these errors, the Company determined in August 2014 to restate its consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011 (including the interim quarterly periods contained within the fiscal years ended December 31, 2013 and 2012) and the fiscal quarter ended March 31, 2014, and that the previously filed financial statements for these periods (including those contained in the Original 2013 Form 10-K and the 2014 First Quarter Form 10-Q) should no longer be relied upon. Contemporaneously with the filing of this Report, the Company is filing (i) an amendment to the Original 2013 Form 10-K (the 2013 Form 10-K/A), which amendment contains restated consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011, and the quarterly reporting periods contained within the fiscal years ended December 31, 2013 and 2012, (ii) an amendment to the Original 2014 First Quarter Form 10-Q (the 2014 First Quarter Form 10-Q/A), which amendment contains restated consolidated interim financial statements for the fiscal quarters ended March 31, 2014 and 2013, and (iii) its delayed Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2014 (the 2014 Second Quarter Form 10-Q), which contains restated consolidated interim financial statements for the fiscal quarterly and year-to-date periods ended June 30, 2013. The corrections of the additional errors in the 2013 Form 10-K/A and the 2014 First Quarter Form 10-Q/A are referred to herein as the Further Restatement.

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The errors corrected by the Further Restatement are as follows:

A majority of revenue from the Company s BioStim SBU is derived from third parties, which is subject to change due to contractual adjustments related to commercial insurance carriers, and may include certain patient co-pay amounts. The Company previously recorded certain co-pay and self-pay amounts as revenue with estimated uncollectible portions being recognized as bad debt expense. Given the collectability of co-pay and self-pay amounts was not reasonably assured, the conditions for revenue recognition had not been met and revenue for those amounts should not have been recognized until collected. Adjustments to correct the foregoing reduce equally both the Company s historical net sales and its sales and marketing expense by approximately $2.2 million, $9.0 million and $6.0 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, and $1.4 million for the fiscal quarter ended March 31, 2014. Additionally, there was $1.4 million in the fiscal quarter ended March 31, 2014 related to contractual amounts from commercial insurance carriers which was incorrectly classified to bad debt expense rather than a reduction of revenue, for a total reduction to bad debt and revenue of $2.8 million for the fiscal quarter ended March 31, 2014. These adjustments have no effect on net income from continuing operations or net income in those periods.

Certain bad debt reserves originally recorded in fiscal years 2011 and 2012 were reversed in incorrect periods in the Original Restatement in connection with the change to sell-through accounting for certain distributors. As a result, sales and marketing expense was understated by approximately $1.5 million and $1.1 million for the fiscal years ended December 31, 2013 and 2012, respectively, and overstated by approximately $2.1 million for the fiscal year ended December 31, 2011.

As part of analyzing collections experience on accounts receivable, the Company identified that it had incorrectly considered certain deferred revenue amounts included in gross accounts receivable when calculating estimated reserves. Specifically, the computation of the contractual allowances and bad debt allowances, which serves to adjust accounts receivable to the estimated collectible amount, incorrectly assumed that some percentage of deferred amounts would be collected, rather than fully deferring these amounts. Adjustments to correct this error resulted in a net decrease in operating income of $0.7 million and $0.2 million for the fiscal years ended December 31, 2013 and 2011, respectively, and a net increase in operating income of $2.1 million for the fiscal year ended December 31, 2012, as well as a net decrease in operating loss of $1.5 million for the fiscal quarter ended March 31, 2014.

As part of the Original Restatement, the Company made certain corrections to prior period excess and obsolete inventory reserves. The effect of these corrections was not considered when determining the adjustments needed to eliminate intercompany profits from inventories in the Original Restatement. Adjustments to correct this error resulted in an increase to cost of sales of $1.1 million, $0.2 million and $0.3 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $3.0 million for the fiscal quarter ended March 31, 2014.

As part of the remediation activities that followed the Original Restatement, the Company expanded its procedures in the second quarter of 2014 to validate the existence of field inventory held by independent

sales representatives and noted that, in many cases, this inventory had higher rates of missing inventory (shrinkage) than previously estimated. To determine whether these higher error rates were pervasive across its field inventory, the Company counted approximately 90% of its field inventory during the third and fourth fiscal quarters of 2014. These counts resulted in the identification of errors relating to previous estimates of shrinkage. Adjustments in the Further Restatement to correct these errors, net of the related effect on previously recorded excess and obsolete inventory reserves, resulted in an increase to cost of sales of $0.4 million, $0.3 million and $0.2 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $0.2 million for the fiscal quarter ended March 31, 2014.

In connection with its remediation efforts associated with the material weakness noted in the Original Restatement related to inventory reserves, including performing a hindsight analysis of previously established reserves, the Company concluded that it was not appropriately calculating inventory reserves, including its consideration of demand assumptions for kits , which contain a variety of piece part components to be used during surgery as well as inventory held by third parties under inventory purchase obligations. Adjustments to correct this error resulted in an increase to cost of sales of $3.2 million, $1.5 million and $0.1 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $2.4 million for the fiscal quarter ended March 31, 2014.

In addition to the adjustments described above, the Company is correcting certain other items. The impact of correcting these items results in a decrease to income tax expense of $0.5 million and $1.1 million for the fiscal years ended December 31, 2013 and 2012, respectively, to correct an income tax payable error that was recorded during the Original Restatement; these adjustments are separate from the tax effect of the errors described above

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In the aggregate, the remaining additional adjustments resulted in a decrease to loss before income taxes of $1.1 million for the fiscal year ended December 31, 2013, a increase to loss before income taxes of $0.1 million for the fiscal year ended December 31, 2012 and a decrease to income before income taxes of $0.7 million for the fiscal year ended December 31, 2011, as well as a decrease to loss before income taxes of $1.6 million for the fiscal quarter ended March 31, 2014.

Evaluation of Disclosure Controls and Procedures

In connection with the preparation of this Report, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Interim 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, 2013, management 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. As a result of these ongoing material weaknesses, our President and Chief Executive Officer and Interim Chief Financial Officer concluded at that time that our disclosure controls and procedures were not effective as of September 30, 2014.

Material Weaknesses in Internal Control over Financial Reporting

In connection with the preparation of this Report, our management, including our President and Chief Executive Officer and our Interim Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2013 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 certain material weaknesses described below, the Company s internal control over financial reporting was not effective as of September 30, 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, 2013:

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

Company personnel were not adequately trained with respect to certain revenue recognition principles applicable under U.S. GAAP that may have led to appropriate consideration of the additional terms entered into outside of the written contractual terms.

A*ccounts receivable reserves.* In connection with our internal control remediation activities that followed the Original 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 prior accounts receivable reserve process and calculations were insufficiently designed to detect a material misstatement.

Inventory reserves. In connection with the Independent Review and 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 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.

Inventory existence. In connection with our internal control remediation activities that followed the Original Restatement, we expanded our procedures to validate the existence of field inventory held by independent sales representatives. In connection with these additional procedures, we identified errors which we believe indicate that the controls relating to the prior inventory counts performed were insufficiently designed to detect a material misstatement.

Foreign subsidiary oversight. In connection with the Independent Review and 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

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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 fiscal year ended December 31, 2013, we determined that our controls over manual journal entries were not effective. 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 there sufficient procedures 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. Because of the foregoing matters, our management has concluded that we did not maintain effective internal control over financial reporting as of September 30, 2014.

Plans for Remediation

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 plans described herein. These remediation efforts are being undertaken under the supervision of the Audit Committee, including a new Chair of the Audit Committee, who joined the Board 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 plan 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 are working to improve procedures with respect to the proper communication, approval, documentation and accounting review of deviations from written sales contracts.

Management s remediation plan 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.

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Management s remediation plan 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; and

We have enhanced the calculation and review of our inventory reserve analysis, including enhancing our model to capture demand considerations at the component level rather than the aggregated kit level, and increasing the involvement of both finance and operational personnel, which we expect to provide better controls to assess excess and obsolete inventory based on the current inventory on hand in relation to the demand forecast and related reserves.

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 plan with respect to controls over existence of field inventory at independent sales rep locations:

We have enhanced and expanded the extent of our physical inventory count procedures to require all piece parts, including those contained within kits, held by independent sales representatives be counted at least annually, in order to thoroughly and timely verify the existence of field inventory.

We have engaged a third party with relevant industry experience to assist in the completion of these expanded procedures, conducted physical counts of Spine Fixation device inventory held on consignment with distributors and hospital customers, and adjusted our inventory reserves to reflect the results of counts the Company completed during 2014 as part of this remediation.

We have also updated and enhanced our inventory management practices and review procedures for such consigned inventory.

Management s remediation plan 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 are evaluating our accounting systems to determine appropriate enhancements, and a plan is being executed that includes upgrading accounting systems at foreign locations.

Management s remediation plan 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, which in some cases have already been implemented, have improved and will continue to improve the effectiveness of our internal control over financial reporting. However, we have not completed all of the corrective processes and procedures identified above. Accordingly, 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 as described above, there have not been any changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2014 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

As previously disclosed, at the time of its divestiture by the Company in 2012, the Company s sports medicine subsidiary, Breg, Inc., 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 were filed in recent years, mostly in California state court, alleging that 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. In connection with the Company s divestiture of Breg, the Company agreed to indemnify Breg s acquirer for Breg s pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. In September 2014, the Company entered into a master settlement agreement that resolves the pending claims with respect to all except one claim pending in a California coordinated proceeding concerning pre-closing sales. 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 have been recorded as an expense in discontinued operations during the fiscal quarter ended June 30, 2014.

The Company is party to certain outstanding legal proceedings, investigations and claims. These matters are described in the 2013 Form 10-K/A. As of the date of this filing, there had been no other material developments in these matters since the filing of the 2013 Form 10-K/A.

Item 1A. Risk Factors

As of the date of this Form 10-Q there had been no material changes to the Company s risk factors from the factors discussed in Part I, Item 1A., Risk Factors in the 2013 Form 10-K/A.

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

Stock Repurchases

Under the stock repurchase program, repurchases are being made from time to time in the open market based on market conditions, securities law limitations and other factors. During the nine months ended September 30, 2014, there were no stock repurchases.

Period	Total Number of Shares Purchased	Average price Paid Per Share	Total Cumulative Number of Shares Purchased under Approved Stock Repurchase Program	Maximum Dollar Value of Shares Allowed to be Purchased under Approved Stock Repurchase Program
May 2013	515,865	$ 26.64	515,865	$ 36,269,366
June 2013	472,650	$ 27.77	988,515	$ 23,131,669
July 2013	449,063	$ 28.04	1,437,578	$ 10,505,778

Total as of September 30, 2014	1,437,578	$ 27.55	1,437,578	$	10,505,778

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Item 6. Exhibits

10.1	Limited Waiver, entered into on August 14, 2014, by and among Orthofix International N.V., Orthofix Holdings, Inc. and certain of its wholly owned subsidiaries, and certain lender parties thereto (filed as an exhibit to the Company s current report on Form 8-K filed August 19, 2014 and incorporated herein by reference).
10.2	Limited Waiver, entered into on September 30, 2014, by and among Orthofix International N.V., Orthofix Holdings, Inc. and certain of its wholly owned subsidiaries, and certain lender parties thereto (filed as an exhibit to the Company s current report on Form 8-K filed October 6, 2014 and incorporated herein by reference).
10.3	Employment Agreement, entered into and effective as of September 4, 2014, between Orthofix Inc. and Doug Rice (filed as an exhibit to the Company s current report on Form 8-K filed September 8, 2014 and incorporated herein by reference).
10.4	Amendment No. 1 to Employment Agreement, entered into and effective as of October 3, 2014, between Orthofix Inc. and Doug Rice (filed as an exhibit to the Company s current report on Form 8-K filed October 6, 2014 and incorporated herein by reference).
10.5*	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan July 2014 Grants (Time-Based Vesting)
10.6*	Form of Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan July 2014 Grants (Time-Based Vesting)
10.7*	Form of Employee Performance Vesting Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan July 2014 Grants
10.8*	Form of Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan July 2014 Grants (Time-Based Vesting)
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 the Orthofix International N.V. Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Condensed Consolidated Statements of Cash Flows and (iv) related notes, detail tagged.

* Filed herewith.

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SIGNATURES

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

ORTHOFIX INTERNATIONAL N.V.

Date: March 30, 2015

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

Date: March 30, 2015

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