

ORTHOFIX INTERNATIONAL N V

Form 10-Q

March 24, 2014

Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(Mark one)

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

For the quarterly period ended June 30, 2013

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 0-19961

**ORTHOFIX INTERNATIONAL N.V.**

(Exact name of registrant as specified in its charter)

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

**Curaçao**  
(State or other jurisdiction of  
incorporation or organization)

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

**7 Abraham de Veerstraat**

**Curaçao**  
(Address of principal executive offices)

**Not applicable**  
(Zip Code)

**599-9-4658525**

(Registrant's telephone number, including area code)

**Not applicable**

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

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

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

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

Large Accelerated filer

Accelerated filer

Non-Accelerated filer  (Do not check if a smaller reporting company)

Smaller Reporting Company

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

As of March 14, 2014, 18,187,194 shares of common stock were issued and outstanding.

**Table of Contents**

**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 June 30, 2013 (this Report or this Form 10-Q) concurrently with the filing of an amendment to its Annual Report on Form 10-K for the year ended December 31, 2012 (the 2012 Form 10-K/A) and an amendment to its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013 (the 2013 First Quarter Form 10-Q/A, and together with the 2012 Form 10-K/A, the Amendments). We experienced substantial delays in filing this Report with the Securities and Exchange Commission (SEC) as a result of issues identified in connection with an independent review by the Audit Committee of the Company's Board of Directors into certain accounting matters, which review led to the restatement of our previously issued consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010, as well as for the interim quarterly period ended March 31, 2013, as well as the correction of additional errors in prior periods. For additional information regarding this restatement and related matters, you should refer to the Amendments being filed contemporaneously with the filing of this Report.

This Report reflects the effects of the restatement of the Company's previously issued condensed consolidated financial statements for the three and six months ended June 30, 2012 in Part I, Item 1, Financial Statements, and Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations in both tabular and textual form. We also expect to file our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2013 (the 2013 Third Quarter Form 10-Q) on the date following the date of this Report, which 2013 Third Quarter Form 10-Q will reflect the effects of the restatement of the Company's previously issued condensed consolidated financial statements for the three and nine months ended September 30, 2012 in Part I, Item 1, Financial Statements, and Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations in both tabular and textual form. We do not plan to amend any previously filed reports in connection with the restatement other than as described above.

For further detail on the financial statement impacts and the adjustments made as a result of the restatement, please see Note 2 to the Condensed Consolidated Financial Statements in Part I, Item 1, Financial Statements of this Report, and Note 2 to the Consolidated Financial Statements in Part II, Item 8, Financial Statements and Supplementary Data of the 2012 Form 10-K/A. We currently expect to file our Annual Report on Form 10-K for the year ended December 31, 2013 by March 31, 2014.

**Table of Contents**

**Table of Contents**

	<b>Page</b>
PART I	
	<b><u>FINANCIAL INFORMATION</u></b>
Item 1.	5
	<b><u>Financial Statements (Unaudited)</u></b>
	5
	<b><u>Condensed Consolidated Balance Sheets as of June 30, 2013 (Unaudited) and December 31, 2012</u></b>
	6
	<b><u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2013 (Unaudited) and 2012</u></b>
	7
	<b><u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2013 (Unaudited) and 2012</u></b>
	8
	<b><u>Notes to Unaudited Condensed Consolidated Financial Statements</u></b>
Item 2.	24
	<b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>
Item 3.	31
	<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b>
Item 4.	32
	<b><u>Controls and Procedures</u></b>
PART II	
	<b><u>OTHER INFORMATION</u></b>
Item 1.	34
	<b><u>Legal Proceedings</u></b>
Item 1A.	34
	<b><u>Risk Factors</u></b>
Item 2.	34
	<b><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></b>
Item 6.	35
	<b><u>Exhibits</u></b>
<b><u>SIGNATURES</u></b>	<b>36</b>

**Table of Contents**

**Forward-Looking Statements**

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans, anticipates, believes, estimates, projects, intends, predicts, potential, continue or similar terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. We undertake no obligation to further update any such statement 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 Audit Committee review and financial restatement described herein and in the 2012 Form 10-K/A 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 non-compliance with certain Nasdaq Stock Market LLC (Nasdaq) listing rules, and related pending hearings proceedings in connection therewith, the expected sales of our products, including recently launched products, unanticipated expenditures, changing relationships with customers, suppliers, strategic partners and lenders, changes to and the interpretation of governmental regulations, the resolution of pending litigation matters (including our indemnification obligations with respect to certain product liability claims against, and the government investigation of, our former sports medicine global business unit) (as further described in the *Legal Proceedings* sections of this report and other reports that we will file in the future), our ongoing compliance obligations under a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services (and related terms of probation) and a deferred prosecution agreement with the U.S. Department of Justice, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry, credit markets and the economy, corporate development and market development activities, including acquisitions or divestitures, unexpected costs or operating unit performance related to recent acquisitions, and other risks described in Item 1A under the heading *Risk Factors* in the 2012 Form 10-K/A, as well as in other reports that we will file in the future.

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements****ORTHOFIX INTERNATIONAL N.V.****Condensed Consolidated Balance Sheets**

(U.S. Dollars, in thousands, except share data)	June 30, 2013 (unaudited)	December 31, 2012 (Restated)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 27,370	\$ 31,055
Restricted cash	20,601	21,314
Trade accounts receivable, less allowance for doubtful accounts of \$10,977 and \$13,543 at June 30, 2013 and December 31, 2012, respectively	90,828	107,312
Inventories	94,941	83,373
Deferred income taxes	33,664	33,450
Prepaid expenses and other current assets	28,993	34,079
<b>Total current assets</b>	<b>296,397</b>	<b>310,583</b>
Property, plant and equipment, net	55,166	53,835
Patents and other intangible assets, net	6,857	7,290
Goodwill	72,758	74,388
Deferred income taxes	19,205	18,881
Other long-term assets	9,067	7,920
<b>Total assets</b>	<b>\$ 459,450</b>	<b>\$ 472,897</b>
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Trade accounts payable	\$ 18,894	\$ 22,575
Other current liabilities	52,679	39,610
<b>Total current liabilities</b>	<b>71,573</b>	<b>62,185</b>
Long-term debt	20,000	20,000
Deferred income taxes	12,326	11,456
Other long-term liabilities	10,324	11,424
<b>Total liabilities</b>	<b>114,223</b>	<b>105,065</b>
Contingencies (Note 16)		
Shareholders' equity:		
Common shares \$0.10 par value; 50,000,000 shares authorized; 18,494,258 and 19,339,329 issued and outstanding as of June 30, 2013 and December 31, 2012, respectively	1,849	1,934
Additional paid-in capital	225,148	246,306
Retained earnings	117,030	114,847
Accumulated other comprehensive income	1,200	4,745
<b>Total shareholders' equity</b>	<b>345,227</b>	<b>367,832</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 459,450</b>	<b>\$ 472,897</b>

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



**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)****For the three and six months ended June 30, 2013 and 2012**

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012 (Restated)	2013	2012 (Restated)
Product sales	\$ 86,633	\$ 101,902	\$ 177,969	\$ 199,510
Marketing service fees	11,647	11,521	23,684	22,849
Net sales	98,280	113,423	201,653	222,359
Cost of sales	20,246	27,547	45,863	48,925
Gross profit	78,034	85,876	155,790	173,434
Operating expenses				
Sales and marketing	44,910	47,075	89,964	94,203
General and administrative	15,204	14,295	33,534	28,865
Research and development	8,551	9,252	14,292	16,302
Amortization of intangible assets	565	580	1,109	1,160
Charges related to U.S. Government resolutions		376		686
	69,230	71,578	138,899	141,216
Operating income	8,804	14,298	16,891	32,218
Other income and expense				
Interest expense, net	(470)	(1,265)	(1,030)	(3,486)
Other income (expense), net	(1,207)	660	3,557	29
	(1,677)	(605)	2,527	(3,457)
Income before income taxes	7,127	13,693	19,418	28,761
Income tax expense	(2,997)	(3,823)	(7,678)	(10,294)
Net income from continuing operations, net of tax	4,130	9,870	11,740	18,467
Discontinued operations (Note 15)				
Gain on sale of Breg, Inc., net of tax		1,040		1,040
Loss from discontinued operations	(9,154)	(5,853)	(13,588)	(5,326)
Income tax benefit	2,707	2,197	4,031	2,480
Net loss from discontinued operations, net of tax	(6,447)	(2,616)	(9,557)	(1,806)
Net Income (loss)	\$ (2,317)	\$ 7,254	\$ 2,183	\$ 16,661
Net income (loss) per common share- basic:				
Net income from continuing operations, net of tax	\$ 0.22	\$ 0.52	\$ 0.61	\$ 0.98
Net income (loss) from discontinued operations, net of tax	(0.34)	(0.14)	(0.50)	(0.10)
Net income (loss) per common share- basic	\$ (0.12)	\$ 0.38	\$ 0.11	\$ 0.88



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

Net income (loss) per common share- diluted:								
Net income from continuing operations, net of tax	\$	0.21	\$	0.51	\$	0.60	\$	0.96
Net income (loss) from discontinued operations, net of tax		(0.33)		(0.14)		(0.49)		(0.09)
Net income (loss) per common share- diluted:	\$	(0.12)	\$	0.37	\$	0.11	\$	0.87
Weighted average number of common shares:								
Basic		19,140,520		18,827,452		19,285,004		18,751,573
Diluted		19,270,044		19,215,984		19,483,715		19,168,940
Comprehensive income (loss)	\$	(2,836)	\$	3,842	\$	(1,362)	\$	15,629
<i>The accompanying notes form an integral part of these condensed consolidated financial statements.</i>								

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****Condensed Consolidated Statements of Cash Flows****For the six months ended June 30, 2013 and 2012**

(Unaudited, U.S. Dollars, in thousands)	Six Months Ended June 30,	
	2013	2012 (Restated)
Cash flows from operating activities:		
Net income	\$ 2,183	\$ 16,661
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	10,209	11,118
Amortization of debt costs	360	1,375
Provision for doubtful accounts	2,486	5,224
Deferred income taxes	222	(3,004)
Share-based compensation	3,437	2,738
Gain on sale of Breg, Inc.		(1,040)
Income tax benefit on employee stock-based awards	758	
Excess income tax benefit on employee stock-based compensation	(82)	(1,156)
Other	2,296	(5,418)
Change in operating assets and liabilities, net of effect of disposition:		
Trade accounts receivable	13,124	(11,482)
Inventories	(12,882)	2,270
Escrow receivable		41,537
Prepaid expenses and other current assets	9,343	1,934
Trade accounts payable	(3,452)	(5,367)
Charges related to U.S. Government resolutions		686
Other current liabilities	8,844	1,539
Long-term assets	(1,521)	
Long-term liabilities	(1,164)	142
<b>Net cash provided by operating activities</b>	<b>34,161</b>	<b>57,757</b>
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(12,826)	(12,794)
Capital expenditures for intangible assets	(651)	(214)
Net proceeds from the sale of Breg, Inc.		153,092
<b>Net cash provided by (used in) investing activities</b>	<b>(13,477)</b>	<b>140,084</b>
Cash flows from financing activities:		
Net proceeds from issuance of common shares	2,188	13,340
Repayments of long-term debt		(168,695)
Repayment of bank borrowings, net	(16)	(831)
Changes in restricted cash	721	(25,831)
Repurchase of treasury shares	(26,868)	
Excess income tax benefit on employee stock-based awards	82	1,156
<b>Net cash used in financing activities</b>	<b>(23,893)</b>	<b>(180,861)</b>
Effect of exchange rate changes on cash	(476)	(98)
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(3,685)</b>	<b>16,882</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>31,055</b>	<b>33,207</b>

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

Cash and cash equivalents at the end of the period	\$ 27,370	\$ 50,089
--	-----------	-----------

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

## **Table of Contents**

### **ORTHOFIX 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 accounting principles generally accepted in the United States ( U.S. ) 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 accounting principles generally accepted in the U.S., 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 six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. The balance sheet at December 31, 2012 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. For further information, refer to the Consolidated Financial Statements and Notes thereto of the 2012 Form 10-K/A. The notes to the unaudited condensed consolidated financial statements are presented on a continuing operations 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 income or shareholders' equity.

###### **(c) Use of estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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 the resolution of U.S. government matters, contractual allowances, doubtful accounts, inventories, taxes, shared-based compensation, and potential goodwill and intangible asset impairment. Actual results could differ from these estimates.

###### **(d) Foreign Currency Translation**

The financial statements for operations outside the United States are generally maintained in their local currency. All foreign currency denominated balance sheet accounts, except shareholders' equity, are translated to U.S. dollars at year 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.

##### **2. Restatement of the Condensed Consolidated Financial Statements**

###### ***Background***

In July 2013, the Audit Committee (the Audit Committee ) of the Company's Board of Directors (the Board ) commenced an independent review with the assistance of outside professionals into whether the Company had properly recognized revenue under U.S. generally accepted accounting principles ( GAAP ) in connection with certain revenue that had been recorded in 2012 and 2011 (the Independent Review ). In conjunction with the Independent Review, the Company concluded that material errors existed in the previously issued financial statements for the fiscal years ended December 31, 2012, 2011 and 2010, as well as for the interim quarterly period ended March 31, 2013. In addition, the Company has identified and corrected errors occurring prior to January 1, 2010 by recognizing a cumulative adjustment to beginning retained earnings in the consolidated statements of changes in shareholders' equity included in the consolidated financial statements filed with the 2012 Form 10-K/A.

In reaching these conclusions, 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

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

respect to certain transactions, (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.

## **Table of Contents**

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 this Form 10-Q and in the 2012 Form 10-K/A, and such determinations are 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.

The correction of these errors had the following impact for the three and six months ended June 30, 2012: decreased net sales by \$6.1 million and \$13.2 million, respectively; and decreased net income from continuing operations by \$4.1 million and \$7.7 million, respectively. The following include descriptions of the significant adjustments to the Company's financial position and results of operations from the previously reported consolidated financial statements.

### ***Distributor Revenue Recognition***

The Company has determined that it previously recognized revenue with respect to certain distributor relationships before all revenue recognition criteria were met. Specifically, the Company has determined that a fixed or determinable sales price did not exist, and/or collection was not reasonably assured, with respect to certain transactions where revenue had previously been recognized at the time of shipment. Specifically, the Company's review revealed arrangements, or extra-contractual terms, with certain of the Company's distributors regarding extended payment terms, return or exchange rights, and contingent payment obligations for sales to such distributors with respect to certain transactions. There were also concessions being made subsequent to the shipment of inventory to the distributors and the related revenue recognition. Based on the results of this review, it was determined that these arrangements were not appropriately evaluated under the appropriate revenue recognition criteria applicable under GAAP.

The Company previously recognized distributor revenue as title and risk of loss passed at either shipment from the Company's facilities or receipt at the distributor's facility, assuming all other revenue recognition criteria had been achieved (the sell-in method). Based on review of all facts and circumstances related to the arrangements described above, the Company determined that in many instances the revenue recognition criteria under the sell-in method were not satisfied at the time of shipment or receipt; specifically, the existence of extra-contractual terms or arrangements caused the Company not to meet the fixed or determinable criteria for revenue recognition in some cases, and in others collectability had not been established. In situations where the Company is unable to reasonably estimate the effects of these extra-contractual terms, it is precluded from recognizing revenue relating to distributor arrangements until the product is delivered to the end customer. This method is commonly referred to as the sell-through revenue recognition method because the vendor does not recognize revenue until the transaction consideration is fixed or determinable, which coincides with the selling of the product through the distribution channel to the end customer. Because the Company does not have reliable information about when its distributors sell the product through to end customers, the Company will use cash collection from distributors as a basis for revenue recognition under the sell-through method. Although in many cases the Company is legally entitled to the accounts receivable at the time of shipment, since the revenue recognition criteria has not been met, the Company has not recognized accounts receivables or any corresponding deferred revenues associated with these transactions.

As part of the review, the Company also considered the accounting treatment for the related cost of sales when distributor revenue is recognized on a sell-through basis. Previously, cost of sales were recognized upon shipment; however, the Company believes the matching of the recognition of costs of sales with revenue is preferred and therefore considered if such costs should be deferred until revenue is recognized on a sell-through basis. In making this assessment, the Company considered the financial viability of its distributors based on their creditworthiness to determine if collectability of amounts sufficient to realize the costs of the products shipped was reasonably assured at the time of shipment to these distributors. In instances where the distributor was determined to be financially viable, the Company determined that costs of sales should be deferred until the revenue is recognized. For those distributors where the Company has concluded that collectability was not reasonably assured, the Company has expensed the related cost of sales upon shipment.

Based on the results of the Independent Review, the Company determined that all distributor transactions should be transitioned to the sell-through basis method of accounting as of the dates described below:

For distributor transactions within the Company's Orthopedics division, the Company has determined that sell-through accounting should be applied within the Brazil subsidiary for all prior periods given the frequency with which the Company conducted business under extra-contractual and undocumented terms, as well as the Company's inability to fully access underlying transactional and other information that would be necessary to evaluate transactions under a sell-in basis. For distributor transactions within the division outside the Brazil subsidiary, there were also sales to four distributors that did not meet the fixed or determinable or collectability revenue recognition criteria and therefore, such sales were adjusted to sell-through accounting in the restatement.



**Table of Contents**

For other distributor transactions within the Company's U.S. Spine division, the Company has determined that sell-through accounting should be applied beginning January 1, 2011. Following its consideration of the information provided from the Independent Review, the Company believes that January 1, 2011 is the date extra-contractual terms became pervasive in the Company's U.S. business, and it is unaware of circumstances existing prior to that date that would require it to broadly apply sell-through accounting to all distributor transactions within the U.S. Spine division. Additionally, there were sales in 2012 and 2011 for which revenue was previously recognized that did not meet the fixed or determinable criteria and the product associated with such sales was subsequently returned in 2013 (i) under the terms of negotiated agreements whereby the Company terminated its relationships with two distributors and (ii) by an additional distributor who returned certain product sold pursuant to a contingent sales arrangement. Such sales represented approximately \$3.3 million for the year ended December 31, 2012. Due to the return of the product, no revenue will be recognized for these transactions.

The Company has determined that stimulation products sold to distributors within the Company's U.S. Spine division during 2012 did not meet the fixed or determinable (and in some cases, collectability) revenue recognition criterion at the time of shipment. Therefore, the Company has determined that sell-through accounting should be applied for these sales. Management also determined that many of these distributors (or affiliates thereof) received commission payments as part of the sales transactions, which the Company previously recorded as sales and marketing expense. The Company has recorded adjustments in the restatement to net these commission expenses against revenue, as they represented product discounts.

The Company has determined that it will prospectively apply sell-through accounting for all remaining distributor arrangements (which entails arrangements within the Company's Orthopedics division outside the Brazil subsidiary) beginning April 1, 2013, the earliest date for which financial statements had not previously been issued by the Company at the time of the determination. Although the Independent Review did not provide information to indicate extra-contractual terms or that historical revenue recognition was inappropriate in these remaining instances, the Company believes the information from the Independent Review indicating that the Company has a history of extra-contractual arrangements for distributor transactions, as described above, provides additional information which should be considered in reassessing the application of sell-through accounting on a prospective basis, particularly given that the Company believes that there is a higher risk associated with distributor arrangements generally.

The effect of adjustments made to the Company's previously filed consolidated statements of operations as a result of these matters for the three and six months ended June 30, 2012 are shown in the tables below. These adjustments also had the following effects on the Company's previously filed December 31, 2012 consolidated balance sheet:

Accounts receivable decreased as of December 31, 2012 by \$41.3 million related to the de-recognition of receivables for which revenue has been deferred and will now be recognized on a sell-through basis, based on cash collections.

Inventory increased as of December 31, 2012 by \$11.0 million to recognize the costs of inventory shipments to distributors determined to be financially viable, as discussed previously.

***Inventory Reserves***

The Company also identified material errors in inventory reserves. One error related to the Company recording an increase of \$1.2 million to the Company's excess and obsolete reserve in the second quarter of 2012 related to a product within the Spine business that was subsequently reversed by the Company in the fourth quarter of 2012. During the Company's review, it was determined that removing the reserve in the fourth quarter of 2012 was not correct; therefore the reserve has been reinstated.

The Company has also determined that certain inconsistencies existed with respect to how the Company previously computed and recorded inventory reserves. As a result, the Company has reviewed the methodologies used to compute and record inventory reserves and determined that errors in the application of GAAP existed in prior periods, which required adjustment in these financial statements. Based on this review, the Company has determined that it previously made reductions to previously recorded reserves based on changes in forecasted demand, which it believes was contrary to guidance set forth in ASC Topic 330, *Inventory* (specifically ASC 330-10-35-14), which 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. The restated consolidated financial statements contain several adjustments to reflect recomputed inventory reserves in each of the relevant periods.



These adjustments resulted in a decrease to inventory (due to an increase in reserves) as of December 31, 2012 of \$14.8 million.

**Table of Contents****Royalties**

The Company also reviewed the accounting for royalties and determined there were royalties classified as sales and marketing expense; however, such royalties were based on sales of products and were paid to doctors who consulted on development of those products. Given these amounts are attributable to the cost of producing our products, we determined they are correctly classified as cost of goods sold.

**Other Adjustments**

In addition to the adjustments recorded to address the Company's errors in accounting for distributor revenue recognition, inventory reserves, and royalties, the Company has identified other errors that are generally not material, individually or in the aggregate, but have been recorded in connection with the restatement.

There were no material impacts to the statements of cash flows for the items above. The results of the adjustments to the Company's previously filed consolidated statements of operations detailed above for the three and six months ended June 30, 2012 are summarized in the tables below. The tax effect of the adjustments is estimated based on the Company's effective tax rate.

(U.S. Dollars, in thousands)	Three Months Ended June 30, 2012						Restated
	Previously Reported	Distributor Revenue	Inventory Reserves	Royalties	Other	Total Adjustments	
Net sales	\$ 119,492	\$ (5,862)	\$	\$	\$ (207)	\$ (6,069)	\$ 113,423
Cost of sales	23,676	(2,101)	3,880	2,079	13	3,871	27,547
Gross profit	95,816	(3,761)	(3,880)	(2,079)	(220)	(9,940)	85,876
Operating expenses							
Sales and marketing	49,810	(527)		(2,079)	(129)	(2,735)	47,075
General and administrative	14,295						14,295
Research and development	9,252						9,252
Amortization of intangibles assets	530				50	50	580
Charges related to U.S. Government resolutions	1,364				(988)	(988)	376
	75,251	(527)		(2,079)	(1,067)	(3,673)	71,578
Operating income	20,565	(3,234)	(3,880)		847	(6,267)	14,298
Other income and (expense)	(605)						(605)
Income before income taxes	19,960	(3,234)	(3,880)		847	(6,267)	13,693
Income tax expense	(5,993)	1,120	1,343		(293)	2,170	(3,823)
Net income from continuing operations, net of tax	\$ 13,967	\$ (2,114)	\$ (2,537)	\$	\$ 554	\$ (4,097)	\$ 9,870

**Table of Contents**

(U.S. Dollars, in thousands)	Six Months Ended June 30, 2012						Restated
	Previously Reported	Distributor Revenue	Inventory Reserves	Royalties	Other	Total Adjustments	
Net sales	\$ 235,534	\$ (13,256)	\$	\$	\$ 81	\$ (13,175)	\$ 222,359
Cost of sales	45,616	(3,572)	2,668	4,205	8	3,309	48,925
Gross profit	189,918	(9,684)	(2,668)	(4,205)	73	(16,484)	173,434
Operating expenses							
Sales and marketing	99,331	(944)		(4,205)	21	(5,128)	94,203
General and administrative	28,865						28,865
Research and development	16,302						16,302
Amortization of intangibles assets	1,060				100	100	1,160
Charges related to U.S. Government resolutions	1,364				(678)	(678)	686
	146,922	(944)		(4,205)	(557)	(5,706)	141,216
Operating income	42,996	(8,740)	(2,668)		630	(10,778)	32,218
Other income and (expense)	(3,457)						(3,457)
Income before income taxes	39,539	(8,740)	(2,668)		630	(10,778)	28,761
Income tax expense	(13,356)	2,209	1,103		(250)	3,062	(10,294)
Net income from continuing operations, net of tax	\$ 26,183	\$ (6,531)	\$ (1,565)	\$	\$ 380	\$ (7,716)	\$ 18,467

**Table of Contents**

The effects of the restatement on the Company's condensed consolidated balance sheet as of December 31, 2012 are as follows:

(Unaudited, U.S. Dollars, in thousands, except share data)	As of December 31, 2012		
	Previously Reported	Adjustments	Restated
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 31,055	\$	\$ 31,055
Restricted cash	21,314		21,314
Trade accounts receivable, less allowances of \$13,543	150,316	(43,004)	107,312
Inventories	88,744	(5,371)	83,373
Deferred income taxes	16,959	16,491	33,450
Prepaid expenses and other current assets	32,056	2,023	34,079
<b>Total current assets</b>	<b>340,444</b>	<b>(29,861)</b>	<b>310,583</b>
Property, plant and equipment, net	51,362	2,473	53,835
Patents and other intangible assets, net	6,880	410	7,290
Goodwill	74,388		74,388
Deferred income taxes	19,904	(1,023)	18,881
Other long-term assets	11,303	(3,383)	7,920
<b>Total assets</b>	<b>\$ 504,281</b>	<b>\$ (31,384)</b>	<b>\$ 472,897</b>
<b>Liabilities and shareholders' equity</b>			
Current liabilities:			
Trade accounts payable	\$ 21,812	\$ 763	\$ 22,575
Other current liabilities	46,985	(7,375)	39,610
<b>Total current liabilities</b>	<b>68,797</b>	<b>(6,612)</b>	<b>62,185</b>
Long-term debt	20,000		20,000
Deferred income taxes	11,456		11,456
Other long-term liabilities	4,930	6,494	11,424
<b>Total liabilities</b>	<b>105,183</b>	<b>(118)</b>	<b>105,065</b>
Contingencies (Note 16)			
Shareholders' equity:			
Common shares \$0.10 par value; 50,000,000 shares authorized; 19,339,329 issued and outstanding	1,934		1,934
Additional paid-in capital	246,111	195	246,306
Retained earnings	148,549	(33,702)	114,847
Accumulated other comprehensive income	2,504	2,241	4,745
<b>Total shareholders' equity</b>	<b>399,098</b>	<b>(31,266)</b>	<b>367,832</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 504,281</b>	<b>\$ (31,384)</b>	<b>\$ 472,897</b>

**Table of Contents**

The effects of the restatements on the Company's condensed consolidated statement of operations and comprehensive income for the three months ended June 30, 2012 are as follows:

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended June 30, 2012		
	Previously Reported	Adjustments	Restated
Product sales	\$ 107,906	\$ (6,004)	\$ 101,902
Marketing service fees	11,586	(65)	11,521
Net sales	119,492	(6,069)	113,423
Cost of sales	23,676	3,871	27,547
Gross profit	95,816	(9,940)	85,876
Operating expenses			
Sales and marketing	49,810	(2,735)	47,075
General and administrative	14,295		14,295
Research and development	9,252		9,252
Amortization of intangible assets	530	50	580
Charges Related to US Government Resolutions	1,364	(988)	376
	75,251	(3,673)	71,578
Operating income	20,565	(6,267)	14,298
Other income and expense			
Interest expense, net	(1,265)		(1,265)
Other income	660		660
	(605)		(605)
Income before income taxes	19,960	(6,267)	13,693
Income tax expense	(5,993)	2,170	(3,823)
Net income from continuing operations, net of tax	13,967	(4,097)	9,870
Discontinued operations (Note 16)			
Gain on sale of Breg, Inc. (net of tax)	1,040		1,040
Loss from discontinued operations	(5,846)	(7)	(5,853)
Income tax benefit	2,044	153	2,197
Net loss from discontinued operations, net of tax	(2,762)	146	(2,616)
Net income	\$ 11,205	\$ (3,951)	\$ 7,254
Net income (loss) per common share- basic:			
Net income from continuing operations, net of tax	\$ 0.74	\$ (0.22)	\$ 0.52
Net loss from discontinued operations, net of tax	(0.15)	0.01	(0.14)
Net income per common share- basic	\$ 0.59	\$ (0.21)	\$ 0.38
Net income (loss) per common share- diluted:			
Net income from continuing operations, net of tax	\$ 0.73	\$ (0.22)	\$ 0.51
Net loss from discontinued operations, net of tax	(0.15)	0.01	(0.14)

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

Net income per common share- diluted	\$	0.58	\$	(0.21)	\$	0.37
<b>Weighted average number of common shares:</b>						
Basic		18,827,452				18,827,452
Diluted		19,215,984				19,215,984
Comprehensive income	\$	6,822	\$	(3,112)	\$	3,710

**Table of Contents**

The effects of the restatements on the Company's condensed consolidated statement of operations and comprehensive income for the six months ended June 30, 2012 are as follows:

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Six Months Ended June 30, 2012		
	Previously Reported	Adjustments	Restated
Product sales	\$ 212,726	\$ (13,216)	\$ 199,510
Marketing service fees	22,808	41	22,849
Net sales	235,534	(13,175)	222,359
Cost of sales	45,616	3,309	48,925
Gross profit	189,918	(16,484)	173,434
Operating expenses			
Sales and marketing	99,331	(5,128)	94,203
General and administrative	28,865		28,865
Research and development	16,302		16,302
Amortization of intangible assets	1,060	100	1,160
Charges Related to US Government Resolutions	1,364	(678)	686
	146,922	(5,706)	141,216
Operating income	42,996	(10,778)	32,218
Other income and expense			
Interest expense, net	(3,486)		(3,486)
Other income	29		29
	(3,457)		(3,457)
Income before income taxes	39,539	(10,778)	28,761
Income tax expense	(13,356)	3,062	(10,294)
Net income from continuing operations, net of tax	26,183	(7,716)	18,467
Discontinued operations (Note 16)			
Gain on sale of Breg, Inc. (net of tax)	1,040		1,040
Loss from discontinued operations	(6,352)	1,026	(5,326)
Income tax benefit	2,350	130	2,480
Net loss from discontinued operations, net of tax	(2,962)	1,156	(1,806)
Net income	\$ 23,221	\$ (6,560)	\$ 16,661
Net income (loss) per common share- basic:			
Net income from continuing operations, net of tax	\$ 1.40	\$ (0.42)	\$ 0.98
Net loss from discontinued operations, net of tax	(0.16)	0.06	(0.10)
Net income per common share- basic	\$ 1.24	\$ (0.36)	\$ 0.88
Net income (loss) per common share- diluted:			
Net income from continuing operations, net of tax	\$ 1.37	\$ (0.41)	\$ 0.96
Net loss from discontinued operations, net of tax	(0.16)	0.07	(0.09)

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

Net income per common share- diluted	\$	1.21	\$	(0.34)	\$	0.87
<b>Weighted average number of common shares:</b>						
Basic		18,751,573				18,751,573
Diluted		19,168,940				19,168,940
Comprehensive income	\$	21,548	\$	(6,030)	\$	15,518



**Table of Contents****3. Inventories**

Inventories are valued at the lower of cost or market, after provision for excess, obsolete or impaired items which is reviewed and updated on a periodic basis by management. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facility in Italy, cost is determined on a weighted-average basis, which approximates the first in, first out method ( FIFO ), due to the high turn-over rate of inventory at this location. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facility in Texas, standard costs, which approximates actual cost on a FIFO basis, is used to value inventory. Standard costs are reviewed annually by management, or more often in the event circumstances indicate a change in cost has occurred. The valuation of work-in-process, finished products, field inventory and consignment inventory includes the cost of materials, labor and production costs. Field inventory represents immediately saleable finished products inventory that is in the possession of the Company's direct sales representatives. Consignment inventory represents immediately saleable finished products located at third party customers, such as distributors and hospitals. Deferred cost of goods sold result from transactions where the Company has shipped product or performed services for which all revenue recognition criteria have not yet been met. Once all revenue recognition criteria have been met, the deferred revenues and associated cost of goods sold are recognized.

Inventories, net of reserves, were as follows:

(US\$ in thousands)	June 30, 2013	December 31, 2012 (Restated)
Raw materials	\$ 8,639	\$ 7,623
Work-in-process	8,112	7,886
Finished products	38,342	28,308
Field inventory	24,815	22,629
Consignment inventory	5,955	6,155
Deferred cost of goods sold	9,078	10,772
<b>Total Inventory</b>	<b>\$ 94,941</b>	<b>\$ 83,373</b>

**4. Patents and other intangible assets**

(US\$ in thousands)	June 30, 2013	December 31, 2012 (Restated)
<b>Cost</b>		
Patents	\$ 40,289	\$ 38,905
Trademarks definite lived	627	657
	40,916	39,562
<b>Accumulated amortization</b>		
Patents	(33,620)	(31,845)
Trademarks definite lived	(439)	(427)
	(34,059)	(32,272)
<b>Patents and other intangible assets, net</b>	<b>\$ 6,857</b>	<b>\$ 7,290</b>

**5. Goodwill**

The following table presents the changes in the net carrying value of goodwill:

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

<b>(US\$ in thousands)</b>	<b>Total</b>
At December 31, 2012	\$ 74,388
Foreign currency	(1,630)
At June 30, 2013	\$ 72,758

**Table of Contents****6. Bank borrowings**

Borrowings under the line of credit consists of borrowings in Euros used to fund international operations. There were no borrowings under such facilities at June 30, 2013 and \$0.1 million at December 31, 2012. The weighted average interest rates on borrowings under the line of credit at December 31, 2012 was 3.70%.

The Company had an unused available line of credit of 5.8 million (\$7.5 million) and 5.8 million (\$7.6 million) at June 30, 2013 and December 31, 2012, 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 ). Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to \$50 million upon satisfaction of certain conditions.

In May 2012, the Company used a portion of the proceeds from the sale of Breg, Inc. ( Breg ) (see Note 15) to repay in full the remaining \$87.5 million balance on the Term Loan Facility and pay down \$57.5 million of amounts outstanding under the Revolving Credit Facility. This use of proceeds was required by the lenders' consent dated April 23, 2012 to the Credit Agreement. As a result of the sale of Breg, Breg ceased to be a subsidiary of the Company and, therefore, Breg was released as a credit party under the Credit Agreement. Additionally, the Company paid \$20 million in June 2012 and \$20 million in September 2012 to reduce amounts outstanding under the Revolving Credit Facility. As a result, at December 31, 2012, the Term Loan Facility had been repaid in full and there was \$20 million outstanding under the Revolving Credit Facility as of June 30, 2013 and December 31, 2012. 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 June 30, 2013 and December 31, 2012, 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 June 30, 2013 and December 31, 2012 was 2.7%.

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, will 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 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, we obtained a Limited Waiver which waived requirements under the Credit Agreement to deliver quarterly financial statements for the fiscal quarters ending on June 30, 2013 and 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 June 30, 2013 and there were no events of default.

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 June 30, 2013 and December 31, 2012 is \$217.1 million and \$171.9 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities

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

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 June 30, 2013 and December 31, 2012 was \$20.6 million and \$21.3 million, respectively.

**Table of Contents**

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 June 30, 2013 and December 31, 2012, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were \$1.5 million and \$1.8 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).

(US\$ in thousands)

As of June 30, 2013	Fair value: favorable (unfavorable)	Balance sheet location
Cross-currency swap	\$ 1,033	Other long-term assets
<b>As of December 31, 2012</b>		
Cross-currency swap	\$ 305	Other long-term assets

(US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Cross-currency swap unrealized gain (loss) recorded in other comprehensive income (loss), net of taxes	\$ 222	\$ (585)	\$ (96)	\$ (76)

*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).

**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

As of June 30, 2013, the Company's financial instruments included cash equivalents, restricted cash, accounts receivable, short-term bank borrowings, accounts payable, long-term secured debt and a cross currency derivative contract. Cash equivalents consist of short-term, highly liquid, income-producing investments, all of which have original maturities of 90 days or less, including money market funds. The carrying

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

value of restricted cash, accounts receivable, short-term bank borrowings 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.

**Table of Contents**

The Company's cross-currency derivative instrument is the only financial instrument recorded at fair value on a recurring basis. This instrument consists of an over-the-counter contract, which is not traded on a public exchange. The fair value of the swap contract is 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 the swap contract as a Level 2 derivative financial instrument. The Company also considers counterparty credit risk and its own credit risk in its determination of all 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:

(US\$ in thousands)	Balance June 30, 2013	Level 1	Level 2	Level 3
Derivative financial instruments (1)				
Cash flow hedges				
Cross-currency swap	\$ 1,033	\$	\$ 1,033	\$

(1) See Note 8, Derivative Instruments

(US\$ in thousands)	Balance December 31, 2012	Level 1	Level 2	Level 3
Derivative financial instruments(1)				
Cash flow hedges				
Cross-currency swap	\$ 305	\$	\$ 305	\$

**10. Comprehensive income (loss)**

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and 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. The components of and changes in accumulated other comprehensive income were as follows:

(US\$ in thousands)	Foreign Currency Translation Adjustments	Fair Value of Cross-Currency Swap	Accumulated Other Comprehensive Income
Balance at December 31, 2012 (Restated)	\$ 4,614	\$ 131	\$ 4,745
Unrealized gain on cross-currency swap, net of tax of \$56		(96)	(96)
Foreign currency translation adjustment (1)	(3,449)		(3,449)
Balance at June 30, 2013	\$ 1,165	\$ 35	\$ 1,200

(1) As the cash generally remains permanently invested in the non-U.S. dollar denominated foreign subsidiaries, no deferred taxes are recognized on the related foreign currency translation adjustment.

Comprehensive income (loss) was comprised of the following components:

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

(US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012 (Restated)	2013	2012 (Restated)
Net income (loss)	\$ (2,317)	\$ 7,254	\$ 2,183	\$ 16,661
Other comprehensive income (loss):				
Unrealized gain (loss) on cross-currency swap, net of tax \$56	222	(585)	(96)	(76)
Foreign currency translation adjustment	(741)	(2,827)	(3,449)	(956)
Total comprehensive income (loss)	\$ (2,836)	\$ 3,842	\$ (1,362)	\$ 15,629



**Table of Contents****11. Earnings per share**

For the three and six months ended June 30, 2013 and 2012, there were no adjustments to net income (loss) for purposes of calculating basic and diluted net income (loss) available to common shareholders. For the three months ended June 30, 2013, potentially dilutive shares totaled 129,524. 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 June 30,		Six Months Ended June 30,	
	2013	2012 (Restated)	2013	2012 (Restated)
Weighted average common shares-basic	19,140,520	18,827,452	19,285,004	18,751,573
Effect of dilutive securities:				
Unexercised stock options net of treasury share repurchase	129,524	388,532	198,711	417,367
Weighted average common shares-diluted	19,270,044	19,215,984	19,483,715	19,168,940

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 996,478 and 768,269 outstanding options not included in the diluted earnings per share computation for the six months ended June 30, 2013 and 2012, 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:

(US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012 (Restated)	2013	2012 (Restated)
Cost of sales	\$ (563)	\$ 106	\$ (276)	\$ 283
Sales and marketing	470	397	906	842
General and administrative	1,530	772	2,705	1,542
Research and development	57	30	102	71
Total	\$ 1,494	\$ 1,305	\$ 3,437	\$ 2,738

For the six months ended June 30, 2013 and 2012, there were no performance requirements for share-based compensation awarded to employees. 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.

During the six months ended June 30, 2013 and 2012, there were 143,444 and 218,324 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 \$7.7 million and \$10.3 million provision for income tax which reflects an effective tax rate of 39.5% and 36.3% on pre-tax income for the six months ended June 30, 2013 and 2012, respectively. For the six months ended June 30, 2012, \$0.4 million of income related to legal settlements is discrete and not included in the foregoing calculation of the effective tax rate. Excluding the impact of various discrete charges, the effective tax rate on continuing operations for the first six months of 2013 and 2012 was 39.5% and 40.3%, respectively.

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

The principal factors affecting the Company's effective tax rate was the Company's mix of earnings among various tax jurisdictions, state taxes and current period losses in certain jurisdictions for which the Company does not currently provide a tax benefit.

The company applies a more likely than not recognition threshold for all tax uncertainties. Accounting guidance only allows the recognition of those tax benefits that have a greater than 50% likelihood of being sustained upon examination by the taxing authorities. As of June 30, 2013 and December 31, 2012, the Company's unrecognized tax benefit was \$0.8 million and \$1.2 million, respectively. In March 2013 the Company settled a \$0.9 million liability that had been previously accrued as of December 31, 2012. The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company's effective tax rate if recognized. As of June 30, 2013, the Company does not expect the amount of unrecognized tax benefits to change significantly over the next twelve months.

**Table of Contents**

Unremitted foreign earnings increased from \$285.3 million at December 31, 2011 to \$292 million at December 31, 2012. The \$292 million includes \$293.8 million in U.S subsidiaries. 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.

**14. Business segment information**

The Company's segment information (as provided below) has been prepared based on the Company's two global business units ( GBU ) reporting segments, Spine and Orthopedics. The accounting policies of the segments are the same as those described in the business segment information found in Note 13 to the Consolidated Financial Statements included in the 2012 Form 10-K/A.

The table below presents external net sales by GBU reporting segment. Net sales include product sales and marketing service fees. Marketing service fees, which are recorded on a net basis, are comprised of fees earned for the marketing of Trinity Evolution<sup>®</sup>, Trinity ELITE and Versashield<sup>®</sup> in spine and orthopedic applications.

(US\$ in thousands)	External Net Sales by GBU Three Months Ended June 30,			
	2013	2012 (Restated)	Reported Decline	Constant Currency Decline
<b>Spine</b>				
Spine Repair Implants and Regenerative Biologics	\$ 33,953	\$ 35,135	(3)%	(10)%
Spine Regenerative Stimulation	34,088	41,759	(18)%	(21)%
Total Spine	68,041	76,894	(12)%	(16)%
Orthopedics	30,239	36,529	(17)%	(5)%
Total Net Sales	\$ 98,280	\$ 113,423	(13)%	(12)%

(US\$ in thousands)	External Net Sales by GBU Six Months Ended June 30,			
	2013	2012 (Restated)	Reported Decline	Constant Currency Decline
<b>Spine</b>				
Spine Repair Implants and Regenerative Biologics	\$ 70,233	\$ 69,528	1 %	1 %
Spine Regenerative Stimulation	67,832	80,549	(16)%	(16)%
Total Spine	138,065	150,077	(8)%	(8)%
Orthopedics	63,588	72,282	(12)%	(11)%
Total Net Sales	\$ 201,653	\$ 222,359	(9)%	(10)%

The table below presents operating income (loss) by GBU reporting segment:

Operating Income (Loss) by GBU (US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012 (Restated)	2013	2012 (Restated)

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

Spine	\$ 15,440	\$ 16,278	\$ 30,121	\$ 38,297
Orthopedics	(1,110)	2,521	930	2,592
Corporate	(5,526)	(4,501)	(14,160)	(8,671)
Total	\$ 8,804	\$ 14,298	\$ 16,891	\$ 32,218

**15. Sale of Breg and Disposition of Sports Medicine GBU**

On April 23, 2012, the Company's subsidiary Orthofix Holdings and Breg entered into a stock purchase agreement (the SPA) with Breg Acquisition Corp. ( Buyer ), a newly formed affiliate of Water Street Healthcare Partners II, L.P., pursuant to which Buyer agreed to acquire from Orthofix Holdings all the outstanding shares of Breg, subject to the terms and conditions contained therein (the

**Table of Contents**

Transaction ). Under the terms of the SPA, upon closing of the sale, Orthofix Holdings and the Company agreed to indemnify Buyer with respect to certain specified matters, including the government investigation and product liability matters regarding a previously owned infusion pump product line, pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. (See Matters Related to the Company's Former Breg Subsidiary and Possible Indemnification Obligations under Note 17 to the Consolidated Financial Statements included in the 2012 Form 10-K/A.) On May 24, 2012 (the Closing Date ), Orthofix Holdings completed the sale of all of the outstanding shares of Breg for \$157.5 million in cash. After adjustments for working capital and indebtedness in accordance with the terms of the SPA, Orthofix Holdings used \$145 million of the net proceeds to prepay outstanding Company indebtedness, as required by a lender consent received in connection with the Company's existing Credit Agreement. As a result of the closing of this Transaction, Breg ceased to be a subsidiary of the Company and, therefore, Breg was released as a credit party under the Credit Agreement. The Company also agreed to enter into certain transition arrangements at the closing, including a transition services agreement pursuant to which the Company agreed to continue to provide administrative operational support for a period of up to twelve months. As a result of the sale of Breg, the Company completed its exit from the Sports Medicine GBU, of which Breg was a significant component.

The portion of indemnification related to post closing claims related to post-closing sales of cold therapy 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 will amortize the fair value of the noncontingent liability ratably over the period of indemnification, which is three years. The Company's obligations under this guarantee were approximately \$1.3 million and \$1.6 million as of June 30, 2013 and December 31, 2012, respectively.

**Gain on Sale of Discontinued Operations**

The following table presents the value of the asset disposition, proceeds received, net of various working capital adjustments and indebtedness and net gain on sale of Breg as shown in the condensed consolidated statement of operations for the year ended December 31, 2012.

(US\$ in thousands)	Total
Cash proceeds	\$ 157,500
Less:	
Working Capital	(7,093)
Transaction related expenses	(4,276)
Fair value of indemnification	(2,000)
Tangible assets	(8,309)
Intangible assets	(28,164)
Goodwill	(106,200)
Gain on sale of Breg before income taxes	1,458
Income tax expense	(113)
Gain on sale of Breg, net of taxes	\$ 1,345

Included in discontinued operations for the three and six months ended June 30, 2013 is 8.8 million and \$12.8 million, respectively, of expense related to the Company's indemnification of certain specified matters described above.

The Company's consolidated financial statements and related footnote disclosures reflect the Sports Medicine GBU as discontinued operations. Income (loss) associated with the Sports Medicine GBU, net of applicable income taxes is shown as income (loss) from discontinued operations for all periods presented in accordance with ASC 205-20, *Discontinued Operations*.

**16. Contingencies**

The Company is a party to certain outstanding legal proceedings, investigations and claims. These matters (including certain matters occurring in 2013) are described in the 2012 Form 10-K/A. There have been no material developments in these matters since the filing of the 2012 Form 10-K/A.

**17. Stock Repurchase Program**

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

On May 8, 2013, the Company announced that the 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

**Table of Contents**

repurchases without prior notice at any time if the Company determines additional repurchases are not warranted. During the fiscal quarter ended June 30, 2013, the Company made total repurchases in an amount equal to \$26.9 million. Between June 30, 2013 and the date of this Form 10-Q, the Company has made additional repurchases in an amount equal to \$12.6 million, all of which additional repurchases occurred in the fiscal quarter ended September 30, 2013.

**18. Subsequent Events**

In August 2013, as a result of the delay in filing this Report and expected delay in filing our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2013, we sought and obtained a Limited Waiver which waived requirements under the Credit Agreement to deliver quarterly financial statements for the fiscal quarters ending on June 30, 2013 and 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.

We have been delinquent in the filing of our Quarterly Reports on Form 10-Q for the fiscal quarters ended June 30, 2013 and September 30, 2013, as a result of which we have not been in compliance with the rules of the Nasdaq Stock Market and are subject to having our stock delisted from trading on Nasdaq. We have been granted a stay of the delisting of our common stock until such time as a Nasdaq Hearings Panel makes a decision on the merits following a hearing, which hearing has been scheduled for March 27, 2014. We expect to file our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2013 on March 24, 2014. We also expect to file our Annual Report on Form 10-K for the year ended December 31, 2013 (which is otherwise due under SEC rules on March 17, 2014) by March 31, 2014. As a result, we currently believe that we will adequately remedy our current non-compliance with Nasdaq's listing rules. However, there can be no assurance that the Nasdaq hearings panel will concur with our belief that we have remedied our prior non-compliance, in which case our common stock could remain subject to delisting by Nasdaq.

## **Table of Contents**

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

The following discussion and analysis addresses the results of our operations which are based upon the consolidated financial statements included herein, which have been prepared in accordance with US GAAP, for the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012. As discussed below and in Part I, Item 1, Financial Statements Note 2 Restatement of Condensed Consolidated Financial Statements, we have restated our previously issued consolidated financial statements for certain prior periods, including the three and six months ended June 30, 2012. These discussions should be read in conjunction with our historical consolidated financial statements and related notes thereto and the other financial information included in this Form 10-Q and in the Amendments.

#### **Restatement of Previously Issued Consolidated Financial Statements**

As described further below and herein, this Form 10-Q reflects the restatement of our consolidated financial statements as of and for the three and six months ended June 30, 2012. The restatement, which also covers prior and subsequent periods to these, corrects errors principally related to our accounting for revenue recognition for sales to distributors, our accounting for inventory reserves and our accounting for royalties. This Management's Discussion and Analysis of Financial Condition and Results of Operations gives effect to the restatement adjustments for the three and six months ended June 30, 2012. See Note 2 to our condensed consolidated financial statements, which accompany the financial statements in Part I, Item 1 of this Report, for further detail regarding the restatement adjustments. In addition, for further information regarding the matters leading to the restatement and related findings respect to our disclosure controls and procedures and internal control over financial reporting, see Part I, Item 4, Controls and Procedures of this Form 10-Q.

#### *Audit Committee Review*

In conjunction with the Independent Review conducted by the Audit Committee described in Note 2 to the condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q, management concluded that errors existed in the Company's previously issued financial statements with respect to the fiscal years ended December 31, 2012, 2011 and 2010, and the fiscal quarter ended March 31, 2013. There were also similar types of errors identified as affecting the Company's previously issued consolidated financial statements for the fiscal years ended December 31, 2009, 2008 and 2007, for which we included restated consolidated financial information for the fiscal years ended December 31, 2009 and 2008 in the Selected Financial Data table of the 2012 Form 10-K/A. Adjustments prior to January 1, 2010 were recognized as a cumulative adjustment to beginning retained earnings in the consolidated statements of changes in shareholders' equity included in the consolidated financial statements included in Item 8 of the 2012 Form 10-K/A.

In reaching these conclusions, we 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



## **Table of Contents**

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.

We 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 this Form 10-Q and the Amendments, and such determinations are 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.

## **General Overview**

We are a diversified, global medical device company focused on developing and delivering innovative repair and regenerative solutions to the spine and orthopedic markets. Our products are designed to address the lifelong bone-and-joint health needs of patients of all ages, helping them achieve a more active and mobile lifestyle. We design, develop, manufacture, market and distribute medical equipment used principally by musculoskeletal medical specialists for orthopedic applications. Our main products are invasive and minimally invasive spinal implant products and related human cellular and tissue based products ( HCT/P products ), non-invasive regenerative stimulation products used to enhance bone growth and the success rate of spinal fusions and to treat non-union fractures, external and internal fixation devices used in fracture repair, limb lengthening and bone reconstruction. Our products also include bone cement and devices for removal of bone cement used to fix artificial implants.

We have administrative and training facilities in the United States ( U.S. ), Brazil, the United Kingdom, France, Germany, Puerto Rico and Italy and manufacturing facilities in the U.S. and Italy. The Spine global business unit ( GBU ) directly distributes products in the U.S. and commencing in the first quarter of 2013 in Germany and commencing in the third quarter of 2013 in Australia. The orthopedics GBU directly distributes products in the U.S., the United Kingdom, Italy, Germany, Switzerland, Austria, France, Belgium, Brazil and Puerto Rico. In several of these and other markets we also distribute our products through independent distributors.

Our condensed consolidated financial statements include the financial results of our Company and our wholly-owned and majority-owned subsidiaries and entities over which we have control. All intercompany accounts and transactions are eliminated in consolidation.

Our reporting currency is the U.S. Dollar. All balance sheet accounts, except shareholders' equity, are translated at period-end exchange rates and revenue and expense items are translated at weighted average rates of exchange prevailing during the period. Gains and losses resulting from foreign currency transactions are included in other income and expense. Gains and losses resulting from the translation of foreign currency financial statements are recorded in the accumulated other comprehensive income component of shareholders' equity.

Our financial condition, results of operations and cash flows are not significantly impacted by seasonality trends. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower volume of such procedures performed in the late summer. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar denominated income and expenditures. During the period, we have used derivative instruments to hedge foreign currency fluctuation exposures. See Item 3, *Quantitative and Qualitative Disclosures About Market Risk*.

We manage our business by our two GBUs, which are comprised of Spine and Orthopedics, supported by our Corporate activities. These GBUs represent the current segments in which our Chief Operating Decision Maker reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information (as provided below) has been prepared based on our two GBU reporting segments. Corporate activities not necessarily identifiable within the two GBUs are recorded as part of Corporate.

### *Spine*

Spine provides a portfolio of repair and regenerative products that allow physicians to successfully treat a variety of spinal conditions. This global business unit specializes in the design, development and marketing of our spine repair products along with regenerative stimulation and biologics products used in spine applications. Spine distributes its products through a network of distributors, sales representatives and affiliates. This GBU uses both direct and distributor sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.



**Table of Contents***Orthopedics*

Orthopedics provides a portfolio of repair and regenerative products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to spine. This global business unit specializes in the design, development and marketing of our orthopedic repair products along with regenerative stimulation and biologics products used in orthopedic applications. Orthopedics distributes its products through a network of distributors, sales representatives and affiliates. This GBU uses both direct and distributor sales representatives to sell orthopedics 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 with the two GBUs.

**GBU Revenues**

The following table displays net sales by GBU for the three and six months ended June 30, 2013 and 2012.

(US\$ in thousands)	External Net Sales by GBU Three Months Ended June 30,			
	2013	2012 (Restated)	Reported Decline	Constant Currency Decline
<b>Spine</b>				
Spine Repair Implants and Regenerative Biologics	\$ 33,953	\$ 35,135	(3)%	(10)%
Spine Regenerative Stimulation	34,088	41,759	(18)%	(21)%
Total Spine	68,041	76,894	(12)%	(16)%
Orthopedics	30,239	36,529	(17)%	(5)%
Total Net sales	\$ 98,280	\$ 113,423	(13)%	(12)%

(US\$ in thousands)	External Net Sales by GBU Six Months Ended June 30,			
	2013	2012 (Restated)	Reported Decline	Constant Currency Decline
<b>Spine</b>				
Spine Repair Implants and Regenerative Biologics	\$ 70,233	\$ 69,528	1 %	1 %
Spine Regenerative Stimulation	67,832	80,549	(16)%	(16)%
Total Spine	138,065	150,077	(8)%	(8)%
Orthopedics	63,588	72,282	(12)%	(11)%
Total Net sales	\$ 201,653	\$ 222,359	(9)%	(10)%

**Table of Contents**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013 (%)	2012 (%) (Restated)	2013 (%)	2012 (%) (Restated)
Net sales	100	100	100	100
Cost of sales	21	24	23	22
Gross profit	79	76	77	78
Operating expenses:				
Sales and marketing	46	42	45	42
General and administrative	15	13	17	13
Research and development	9	8	7	7
Amortization of intangible assets	1	1	1	1
Charges related to U.S. Government inquiries		1		1
Operating income (loss)	9	13	8	14
Net income (loss)	(2)	6	1	7

**Three Months Ended June 30, 2013 Compared to Three Months Ended June 30, 2012**

Net sales decreased \$15.1 million to \$98.3 million in the second quarter of 2013 compared to \$113.4 million for the same period last year. The impact of foreign currency decreased sales by \$1.0 million during the second quarter of 2013 when compared to the second quarter of 2012.

*Sales*

Net sales in our Spine GBU decreased to \$68.0 million in the second quarter of 2013 compared to \$76.9 million for the same period last year, a decrease of \$8.9 million. The decrease in Spine's net sales was primarily the result of a 18% decrease in the sales of our Regenerative Stimulation products used in Spine applications when compared to the prior year. Revenue from our Repair Implants and Regenerative Biologics revenue products in the second quarter of 2013 decreased 3% when compared to the same period in the prior year.

Net sales in our Orthopedics GBU decreased 17% to \$30.2 million in the second quarter of 2013 compared to \$36.5 million for the same period last year. Historically, for most distributor transactions within our Orthopedics GBU, other than distributors within Brazil and four other distributors that did not meet the fixed or determinable or collectability revenue recognition criteria, we recorded revenue on the sell-in accounting basis. However, as described more fully in Note 2 to the Consolidated Financial Statements, we have reassessed our application of distributor revenue recognition and have applied sell-through accounting for distributor transactions within the Orthopedic GBU on a prospective basis beginning on April 1, 2013 which caused the majority of the decrease in net sales in the second quarter of 2013 compared to the second quarter of 2012.

*Gross Profit* Our gross profit decreased \$7.9 million to \$78.0 million in the second quarter of 2013 compared to \$85.9 million for the same period last year. Gross profit as a percent of net sales in the second quarter of 2013 was 79.4% for the second quarter of 2013 and 75.7% for 2012 during the same period. This decrease was primarily attributable to the decline in sales of our Regenerative Stimulation products which have a higher gross margin compared to our other products.

*Sales and Marketing Expense* Sales and marketing expense, which includes commissions and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense decreased \$2.2 million, to \$44.9 million in the second quarter of 2013 compared to \$47.1 million in the second quarter of 2012. As a percent of net sales, sales and marketing expense was 45.7% and 41.5% in the second quarter of 2013 and 2012, respectively. This increase as a percent of sales was due to higher commissions as a percent of sales in the second quarter 2013 compared to the second quarter of 2012.

*General and Administrative Expense* General and administrative expense increased \$0.9 million, or 6%, in the second quarter of 2013 to \$15.2 million compared to \$14.3 million in the second quarter of 2012 which was primarily due to management succession charges. General and administrative expense as a percent of net sales was 15.5% in the second quarter of 2013 compared to 12.6% for the same period last year.

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

*Research and Development Expense* Research and development expense decreased \$0.7 million in the second quarter of 2013 to \$8.6 million compared to \$9.3 million in the second quarter of 2012. The decrease in research and development expenses in the second quarter of 2013 compared to the same period in the prior year was primarily due to a \$3.1 million charge for an arbitration resolution related to a 2008 co-development agreement in 2012, partially offset by a \$2 million investment with Musculoskeletal Transplant Foundation ( MTF ) for the development and commercialization of the next generation cell-based bone growth technology in 2013. As a percent of net sales, research and development expense was 8.7% in the second quarter of 2013 compared to 8.2 % for the same period last year.

**Table of Contents**

*Amortization of Intangible Assets* Amortization of intangible assets was \$0.6 million in the second quarter of 2013 and for the same period last year.

*Charges Related to U.S. Government Resolutions* We recorded no charge in the second quarter of 2013 and a \$0.4 million charge in the same period of the prior year, which represents imputed interest accrued on the previously disclosed settlements in principle of the U.S. government investigations and related qui tam complaints related to our regenerative stimulation business and Blackstone Medical Inc.

*Interest Expense, net* Interest expense, net was \$0.5 million for the second quarter of 2013 compared to \$1.3 million for the same period last year, primarily as the result of a lower year over year outstanding debt balance repaid with a portion of the proceeds from the sale of Breg.

*Other Income and Expense* Other income (expense) was \$(1.2) million and \$0.7 million for the second quarters of 2013 and 2012, respectively. The fluctuation can be mainly attributable to the effect of foreign exchange. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) 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 42.1% and 28.7% during the second quarters of 2013 and 2012, respectively. For the three months ended June 30, 2012, \$0.4 million of income related to legal settlements is discrete and not included in the foregoing calculation of the effective tax rate. When adjusted for various discrete items, the effective tax rate for the second quarter of 2013 and 2012 was 41.8% and 41.2%, respectively. These rates are affected by the mix of earnings among various tax jurisdictions and losses incurred in a number of foreign jurisdictions, for which we do not currently recognize a tax benefit. We do not believe that it is more likely than not that we will generate sufficient future income in these jurisdictions to allow for the utilization of these losses before their expiration.

*Discontinued operations* Discontinued operations in 2013 include approximately \$3.7 million of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to its former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters. Discontinued operations in the second quarter of 2012 includes the results of our Sports Medicine GBU up to May 24, 2012 (the closing date of the sale of Breg), net of income taxes. The second quarter of 2012 also includes the gain on the sale of Breg, of \$1.0 million, net of income taxes.

*Net Income (loss)* Net income (loss) for the second quarter of 2013 was a net (loss) of \$(2.3) million, or \$(0.12) per basic and diluted share, compared to net income of \$7.3 million, or \$0.38 per basic share and \$0.37 per diluted share for the same period last year.

**Six Months Ended June 30, 2013 Compared to Six Months Ended June 30, 2012**

Net sales decreased \$20.7 million to \$201.7 million in the first six months of 2013 compared to \$222.4 million for the same period last year. The impact of foreign currency increased sales by \$1.5 million during the first six months of 2013 when compared to the same period of 2012.

*Sales*

Net sales in our Spine GBU decreased to \$138.1 million in the first six months of 2013 compared to \$150.1 million for the same period last year, a decrease of \$12.0 million. The decrease in Spine's net sales was primarily the result of a 16% decrease in sales of our Spine Regenerative Stimulation revenue products in the first six months of 2013 when compared to the same period in the prior year. Sales were slightly positively impacted by a 1% growth in Spine Repair Implants and Regenerative Biologics as compared to same period in the prior year.

Net sales in our Orthopedics GBU decreased 12%, to \$63.6 million in the first six months of 2013 compared to \$72.3 million for the same period last year. Historically, for most distributor transactions within our Orthopedics GBU, other than distributors within Brazil and four other distributors that did not meet the fixed or determinable or collectability revenue recognition criteria, we recorded revenue on the sell-in accounting basis. However, as described more fully in Note 2 to the Condensed Consolidated Financial Statements, we have reassessed our application of distributor revenue recognition and have applied sell-through accounting for distributor transactions within the Orthopedic GBU on a prospective basis beginning on April 1, 2013 which caused the majority of the decrease in net sales in the second quarter of 2013. This was the primary reason for the decrease in sales in the first six months of 2013 compared to the first six months of 2012.

*Gross Profit* Our gross profit decreased \$17.6 million to \$155.8 million in the first six months of 2013, compared to \$173.4 million for the same period last year. Gross profit as a percent of net sales in the first six months of 2013 was 77.3% for the first six months of 2013 and 78.0% in 2012 during the same period. This decrease was primarily attributable to the decline in sales of our Regenerative Stimulation products which have a higher gross margin compared to our other products.



**Table of Contents**

**Sales and Marketing Expense** Sales and marketing expense, which includes commissions and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense decreased \$4.2 million, to \$90.0 million in the first six months of 2013 compared to \$94.2 million in the first six months of 2012. As a percent of net sales, sales and marketing expense was 44.6% and 42.4% in the first six months of 2013 and 2012, respectively. This increase as a percent of sales was due to higher commissions as a percent of sales in the first six months of 2013 compared to the first six months of 2012.

**General and Administrative Expense** General and administrative expense increased \$4.6 million, or 15.9%, in the first six months of 2013 to \$33.5 million compared to \$28.9 million in the first six months of 2012. General and administrative expense as a percent of net sales was 16.6% in the first six months of 2013 compared to 13.0% for the same period last year. The increase is attributable primarily to management succession charges and increased legal fees.

**Research and Development Expense** Research and development expense decreased \$2.0 million in the first six months of 2013 to \$14.3 million compared to \$16.3 million for the same period last year. As a percent of sales, research and development expense was 7.1% in the first six months of 2013 compared to 7.3% for the same period last year. The decrease in research and development expenses in the first six months of 2013 compared to the same period in the prior year was due to a \$3.1 million charge for an arbitration resolution related to a 2008 co-development agreement and a \$1 million investment with Musculoskeletal Transplant Foundation ( MTF ) for the development and commercialization of the next generation cell-based bone growth technology in 2012 offset by a \$2 million investment with MTF in 2013 along with the timing of spending related to our ongoing research, development and clinical activities.

**Amortization of Intangible Assets** Amortization of intangible assets was \$1.1 million in the first six months of 2013 compared to \$1.2 million for the same period in 2012.

**Charges Related to U.S. Government Resolutions** We recorded no charge in the second quarter of 2013 and a \$0.7 million charge in the same period of the prior year, which represents imputed interest accrued on the previously disclosed settlements in principle of the U.S. government investigations and related qui tam complaints related to our regenerative stimulation business and Blackstone Medical Inc.

**Interest Expense, net** Interest expense, net was \$1.0 million for the first six months of 2013 compared to \$3.5 million for the same period last year, primarily as the result of a lower rate of effective interest and a lower year over year outstanding debt balance repaid with a portion of the proceeds from the sale of Breg, Inc.

**Other Income and Expense** Other income, net was \$3.6 million for the first six months of 2013 and was \$0.1 million compared to the same period of 2012, respectively. The fluctuation can be mainly attributable to our receipt of \$4.4 million cash 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. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) 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 39.5% and 36.3% during the first six months of 2013 and 2012, respectively. For the six months ended June 30, 2012, \$0.4 million of income related to legal settlements is discrete and not included in the foregoing calculation of the effective tax rate. When adjusted for various discrete items, the effective tax rate for the first six months of 2013 and 2012 was 39.5% and 40.3%, respectively. These rates are affected by the mix of earnings among various tax jurisdictions and losses incurred in a number of foreign jurisdictions, for which we do not currently recognize a tax benefit. We do not believe that it is more likely than not that we will generate sufficient future income in these jurisdictions to allow for the utilization of these losses before their expiration.

**Discontinued operations** Discontinued operations in the first six months of 2013 include approximately \$8.1 million of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to its former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters. Discontinued operations in the first six months of 2012 includes the results of our Sports Medicine GBU up to May 24, 2012 (the closing date of the sale of Breg), net of income taxes. The first six months of 2012 also includes the gain on the sale of Breg, of \$1.0 million, net of income taxes.

**Net Income (loss)** Net income for the first six months of 2013 was \$2.2 million, or \$0.11 per basic and diluted share, compared to net income of \$16.7 million, or \$0.88, per basic share and \$0.87 per diluted share for the same period last year.

**Liquidity and Capital Resources**

Cash and cash equivalents including Restricted Cash at June 30, 2013 were \$48.0 million, of which \$20.6 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$52.4 million at



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

December 31, 2012, of which \$21.3 million was subject to certain restrictions under the senior secured credit agreement discussed below.

**Table of Contents**

Net cash provided by operating activities was \$34.2 million and \$57.8 million for the six months ended June 30, 2013 and 2012, respectively. Net cash provided by operating activities is comprised of net income, non-cash items (including depreciation and amortization, provision for doubtful accounts, share-based compensation and deferred income taxes) and changes in working capital. Net income decreased \$14.5 million to net income of \$2.2 million for the six months ended June 30, 2013 from a net income of \$16.7 million for the comparable period in the prior year. Non-cash items for the six months ended June 30, 2013 increased \$9.8 million to \$19.7 million compared to non-cash items of \$9.8 million in the same period of 2012. Working capital accounts provided \$12.3 million and \$31.3 million of cash for the six months ended June 30, 2013 and 2012, respectively. For the six months ended June 30, 2013, working capital accounts were impacted by \$41.5 million in cash we received from the Blackstone escrow fund which was recorded in Restricted Cash in accordance with the credit facility. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory reflect days sales in receivables of 79 days at June 30, 2013 and 87 days at June 30, 2012, and inventory turns of 1.0 times as of June 30, 2013 and 1.3 times as of June 30, 2012.

Net cash used by investing activities was \$13.5 million for the six months ended June 30, 2013 compared to net cash provided by investing activities of \$140.1 million for the six months ended June 30, 2012. During the second quarter of 2012, we sold Breg, Inc. for net proceeds of \$153.1 million. During the six months ended June 30, 2013 and 2012, we invested \$13.5 million and \$13.0 million in capital expenditures, respectively.

Net cash used in financing activities was \$23.9 million for the six months ended June 30, 2013 compared to \$180.9 million for the six months ended June 30, 2012. During the six months ended June 30, 2013, we made no repayments on our revolving debt as compared to \$168.7 million during the six months ended June 30, 2012. Our restricted cash balance usage of \$25.8 million in the six months ended June 30, 2012 primarily related to the cash received from the Blackstone escrow fund which was recorded in Restricted Cash in accordance with the credit facility. Our restricted cash balance decreased \$0.7 million in the six months ended June 30, 2013. During the six months ended June 30, 2013 and 2012, we received proceeds of \$2.2 million and \$13.3 million, respectively, from the issuance of 143,444 shares and 218,324 shares, respectively, of our common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the three months ended June 30, 2013 we purchased 988,515 of our outstanding shares associated with the stock repurchase program for a total of \$26.9 million.

On August 30, 2010, our wholly-owned U.S. holding company, Orthofix Holdings, Inc. ( "Orthofix Holdings" ) entered into a Credit Agreement (the "Credit Agreement" ) with certain of our 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, \$200.0 million secured revolving credit facility (the "Revolving Credit Facility" ), and a five year, \$100.0 million secured term loan facility (the "Term Loan Facility" ), and together with the Revolving Credit Facility, the "Credit Facilities" ). Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to \$50 million upon satisfaction of certain conditions.

In May 2012, we used a portion of the proceeds from the sale of Breg, Inc. to repay the \$87.5 million remaining balance on the Term Loan Facility and pay down \$57.5 million of amounts outstanding under the Revolving Credit Facility. This use of proceeds was required by the lenders' consent dated April 23, 2012 to the Credit Agreement. Additionally, we paid \$20 million in June 2012 and \$20 million in September 2012 to reduce amounts outstanding under the Revolving Credit Facility.

As of June 30, 2013, the Term Loan Facility had been repaid in full and there was \$20 million outstanding 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 leverage ratio with respect to the immediately preceding four fiscal quarters. As of June 30, 2013 and December 31, 2012, 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 June 30, 2013 and December 31, 2012 was 2.7%.

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, will 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.



---

**Table of Contents**

The Credit Agreement as amended requires us 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 June 27, 2013, we obtained a Limited Waiver which waived requirements under the Credit Agreement with the minimum Fixed Charge Coverage Ratio for the twelve month period ending on June 30, 2013. Also on, August 14, 2013, we obtained a Limited Waiver which waived requirements under the Credit Agreement to deliver quarterly financial statements for the fiscal quarters ending on June 30, 2013 and 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. We believe we were in compliance with the affirmative and negative covenants at June 30, 2013 and there were no events of default.

Certain of our 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. Our 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 June 30, 2013 and December 31, 2012 was \$217.1 million and \$171.9 million, respectively. In addition, the Credit Agreement restricts us and our 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 June 30, 2013 and December 31, 2012 was \$20.6 million and \$21.3 million, respectively.

At June 30, 2013, we had no outstanding bank borrowings and unused available line of credit of approximately 5.8 million (\$7.5 million) under the line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

On May 8, 2013, the Company announced that the 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 June 30, 2013, the Company made total repurchases in an amount equal to \$26.9 million. Between June 30, 2013 and the date of this Form 10-Q, the Company has made additional repurchases in an amount equal to \$12.6 million, all of which additional repurchases occurred in the fiscal quarter ended September 30, 2013.

We believe that current cash balances together with projected cash flows from operating activities, the availability of the \$180 million revolving credit facility, the available Italian line of credit and our 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.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to certain market risks as part of our 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. We use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of June 30, 2013, we had a currency swap in place to minimize foreign currency exchange risk related to a 28.7 million (\$37.3 million translated at the June 30, 2013 foreign exchange rate) intercompany note. As of June 30, 2013 the fair value of the currency swap was approximately \$1 million and is recorded in other long-term assets.

We are exposed to interest rate risk in connection with our 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 June 30, 2013, \$20 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 2.50%. The margin is adjusted based upon the measurement of the consolidated leverage ratio of our Company and our subsidiaries with respect to the immediately preceding four fiscal quarters. As of June 30, 2013, our effective interest rate on our Credit Facilities was 2.7%. Based on the balance outstanding under the Credit Facilities as of June 30, 2013, an immediate change of one percentage point in the applicable interest rate on the Revolving Credit Facility would cause a change in interest expense of approximately \$0.2 million annually.

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

Our 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. We are subject to cost of goods currency exposure when we produce products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. We are 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 June 30, 2013, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million (\$30.2 million). We recorded a foreign currency loss during the six months ended June 30, 2013 of \$0.4 million related to this un-hedged long-term intercompany note in accumulated other comprehensive income during 2013, which resulted from the strengthening of the U.S. dollar against the Euro during the period. For the six months ended June 30, 2013, we recorded a foreign currency loss of \$0.4 million on the statement of operations resulting from gains and losses in foreign currency transactions.

---

**Table of Contents**

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

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-Q. As described below, management has identified material weaknesses in our internal control over financial reporting, which is an integral component of our disclosure controls and procedures. As a result of those material weaknesses, our President and Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of June 30, 2013.

**Material Weaknesses in Internal Control over Financial Reporting**

In connection with management's evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2013, our management, including our President and Chief Executive Officer and our Chief Financial Officer, concluded that, because of the material weaknesses described below, our internal control over financial reporting was not effective as of June 30, 2013.

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 June 30, 2013:

*Revenue recognition practices for sales to the Company's distributors.* We have 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 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 GAAP that may have led to appropriate consideration of the additional terms entered into outside of the written contractual terms.

*Inventory reserves.* 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 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 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.

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

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

## **Table of Contents**

Some or all of the material weaknesses described above resulted in material misstatements in our annual and interim consolidated financial statements. Because of the foregoing matters, our management has concluded that we did not maintain effective internal control over financial reporting as of June 30, 2013.

### **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.

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 will take into account the nature of our business and the geographies in which we conduct it. We are also updating our code of conduct, and all our employees will be required to annually acknowledge their commitment to adhering to its provisions. We also will inform 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 developing a plan for remediation of the ineffective internal control over financial reporting described above. In addition, we have designed and plan to implement, and in some cases have already implemented, 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 are in the process of training sales management 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 established and hired a new Senior Manager of Revenue position in 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 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 period, subsequent write-ups based on demand are not recognized; and



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

We are implementing additional review of our inventory reserve analysis, including the involvement of both finance and operational executives, and more analysis of days inventory on hand at the product line level, 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 reserve.

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

We have changed our structure so that all of our subsidiaries' accounting functions now report to the VP, Controller within the corporate accounting function, which we believe will provide additional corporate-level oversight of their activities;

**Table of Contents**

We have established and hired a Director of Controls and Process Improvement, whose primary duties are the design and implementation of internal controls 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.

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 June 30, 2013 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION****Item 1. Legal Proceedings**

See Note 16, Contingencies, to our unaudited condensed consolidated financial statements contained in Part I, Item 1, Financial Statements, of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

**Item 1A. Risk Factors**

As of the date of this Form 10-Q, there had been no material changes to our risk factors from the factors discussed in Part I, Item 1A, Risk Factors in the 2012 Form 10-K/A.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds*****Stock Repurchases Made in the Quarter***

Under our 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. The following table includes repurchases made under this program during the second quarter of 2013.

Period	Total Number of Shares Purchased	Average price Paid Per Share	Total Number of Shares Purchased under Approved Stock Repurchase Program	Maximum Dollar Value of Shares Yet to be Purchased under Approved Stock Repurchase Program
May 2013	515,865	\$ 26.64	515,865	\$ 36,269,366

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

June 2013	472,650	\$ 27.77	988,515	\$ 23,131,669
Total for period ending June 30, 2013	988,515	\$ 27.28	988,515	\$ 23,131,669

**Table of Contents**

**Item 6. Exhibits**

- 10.1 Letter Agreement, dated May 9, 2013, between Orthofix Inc. and Vicente Trelles (filed as an exhibit to the Company's current report on Form 8-K filed May 14, 2013 and incorporated herein by reference).
- 10.2 Letter Agreement, entered into on June 18, 2013, between Orthofix Inc. and Brian McCollum (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2013 and incorporated herein by reference).
- 31.1\* Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
- 31.2\* Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
- 32.1\* Section 1350 Certification of Chief Executive Officer.
- 32.2\* Section 1350 Certification of Chief Financial Officer.
- 101\* The following materials from the Orthofix International N.V. Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 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.

**Table of Contents**

**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 24, 2014

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

Date: March 24, 2014

By: /s/ Emily V. Buxton  
Name: Emily V. Buxton  
Title: Chief Financial Officer