ORTHOFIX INTERNATIONAL N V
Form 10-Q
March 25, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 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)

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 x No

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

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

Large Accelerated filer	x	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 x 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 September 30, 2013 (this Report or this Form 10-Q) following the filing on March 24, 2014 of an amendment to its Annual Report on Form 10-K for the year ended December 31, 2012 (the 2012 Form 10-K/A), 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), and its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013. 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 filed on March 24, 2014.

This Report reflects 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

		Page
PART I	FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited)	5
	Condensed Consolidated Balance Sheets as of September 30, 2013 (unaudited) and December 31, 2012	5
	Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three months ended September 30, 2013 (unaudited) and 2012 (unaudited)	6
	Condensed Consolidated Statements of Cash Flows for the three months ended September 30, 2013 (unaudited) and 2012 (unaudited)	7
	Notes to Condensed Consolidated Financial Statements	8
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	33
Item 4.	Controls and Procedures	33
PART II	OTHER INFORMATION	
Item 1.	Legal Proceedings	36
Item 1A.	Risk Factors	36
Item 6.	Exhibits	37
SIGNATURES		38

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 or continue or other comparable te 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 Amendments 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)	September 30, 2013 (unaudited)	December 31, 2012 (Restated)
Assets		
Current assets:		
Cash and cash equivalents	$ 22,219	$ 31,055
Restricted cash	22,732	21,314
Trade accounts receivable, less allowance for doubtful accounts of $11,460 and $13,543 at September 30, 2013 and December 31, 2012, respectively	75,252	107,312
Inventories	100,204	83,373
Deferred income taxes	34,053	33,450
Prepaid expenses and other current assets	27,313	34,079
Total current assets	281,773	310,583
Property, plant and equipment, net	55,762	53,835
Patents and other intangible assets, net	9,821	7,290
Goodwill	55,405	74,388
Deferred income taxes	19,911	18,881
Other long-term assets	7,386	7,920
Total assets	$ 430,058	$ 472,897
Liabilities and shareholders equity		
Current liabilities:		
Trade accounts payable	$ 14,710	$ 22,575
Other current liabilities	51,308	39,610
Total current liabilities	66,018	62,185
Long-term debt	20,000	20,000
Deferred income taxes	12,834	11,456
Other long-term liabilities	12,149	11,424
Total liabilities	111,001	105,065
Contingencies (Note 16)		
Shareholders equity:		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,101,476 and 19,339,329 issued and outstanding as of September 30, 2013 and December 31, 2012, respectively	1,810	1,934

Additional paid-in capital		215,081		246,306
Retained earnings		97,208		114,847
Accumulated other comprehensive income		4,958		4,745
Total shareholders equity		319,057		367,832
Total liabilities and shareholders equity	$	430,058	$	472,897

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 nine months ended September 30, 2013 and 2012

naudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012 (Restated)	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012 (Restated)
oduct sales	$ 81,061	$ 96,552	$ 259,030	$ 296,062
arketing service fees	11,677	11,305	35,361	34,154
et sales	92,738	107,857	294,391	330,216
ost of sales	23,920	24,384	69,783	73,309
ross profit	68,818	83,473	224,608	256,907
perating expenses				
les and marketing	42,382	43,022	132,346	137,225
eneral and administrative	13,202	13,850	46,736	42,715
esearch and development	6,361	6,858	20,653	23,160
mortization of intangible assets	616	565	1,725	1,725
osts related to the accounting review and restatement	2,664		2,664	
npairment of goodwill	19,193		19,193	
harges related to U.S. Government resolutions		373		1,059
	84,418	64,668	223,317	205,884
perating income (loss)	(15,600)	18,805	1,291	51,023
ther income and expense				
terest expense, net	(555)	(464)	(1,585)	(3,950
ther income (expense), net	(1,481)	(1,021)	2,076	(992
	(2,036)	(1,485)	491	(4,942
come (loss) before income taxes	(17,636)	17,320	1,782	46,081
come tax (expense)	(448)	(6,746)	(8,126)	(17,040
et income (loss) from continuing operations, net of tax	(18,084)	10,574	(6,344)	29,041
scontinued operations (Note 15)				
ain on sale of Breg, Inc., net of tax		221		1,261
oss from discontinued operations	(3,041)	(9,048)	(16,629)	(14,374
come tax benefit	1,303	3,269	5,334	5,749
et loss from discontinued operations, net of tax	(1,738)	(5,558)	(11,295)	(7,364

et Income (loss)	$	(19,822)	$	5,016	$	(17,639)	$	21,677
et income (loss) per common share-basic:								
et income (loss) from continuing operations, net of tax	$	(1.00)	$	0.55	$	(0.34)	$	1.54
et (loss) from discontinued operations, net of tax		(0.10)		(0.29)		(0.60)		(0.39
et income (loss) per common share-basic	$	(1.10)	$	0.26	$	(0.94)	$	1.15
et income (loss) per common share-diluted:								
et income (loss) from continuing operations, net of tax	$	(1.00)	$	0.54	$	(0.34)	$	1.51
et (loss) from discontinued operations, net of tax		(0.10)		(0.29)		(0.60)		(0.38
et income (loss) per common share-diluted:	$	(1.10)	$	0.25	$	(0.94)	$	1.13
eighted average number of common shares:								
asic		18,142,935		19,078,590		18,897,887		18,861,374
luted		18,142,935		19,533,021		18,897,887		19,300,263
omprehensive income (loss)	$	(16,064)	$	6,440	$	(17,426)	$	22,069

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Cash Flows

For the nine months ended September 30, 2013 and 2012

(Unaudited, U.S. Dollars, in thousands)	**Nine Months Ended September 30, 2013**	**2012 (Restated)**
Cash flows from operating activities:		
Net income (loss)	$ (17,639)	$ 21,677
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	15,459	15,615
Amortization of debt costs	540	1,556
Provision for doubtful accounts	4,225	5,919
Deferred income taxes	(223)	(5,342)
Share-based compensation	4,714	4,834
Impairment of goodwill	19,193	
Gain on sale of Breg, Inc.		(1,261)
Income tax benefit on employee stock-based awards	795	
Excess income tax benefit on employee stock-based compensation	(82)	(2,321)
Other	(520)	(3,353)
Change in operating assets and liabilities, net of effect of disposition:		
Trade accounts receivable	27,758	(14,169)
Inventories	(11,596)	325
Escrow receivable		41,537
Prepaid expenses and other current assets	5,541	(771)
Trade accounts payable	(8,028)	985
Charges related to U.S. Government resolutions		1,059
Other current liabilities	13,040	1,876
Long-term assets	(313)	(1,093)
Long-term liabilities	(912)	1,322
Net cash provided by operating activities	51,952	68,395
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(19,427)	(18,212)
Capital expenditures for intangible assets	(4,525)	(422)
Net proceeds from the sale of Breg, Inc.		153,773
Net cash provided by (used in) investing activities	(23,952)	135,139
Cash flows from financing activities:		
Net proceeds from issuance of common shares	3,431	24,406
Repayments of long-term debt		(188,695)
Repayment of bank borrowings, net	(16)	(1,036)

Changes in restricted cash	(1,371)	(20,219)
Repurchase of treasury shares	(39,494)	
Excess income tax benefit on employee stock-based awards	82	2,321
Net cash used in financing activities	(37,368)	(183,223)
Effect of exchange rate changes on cash	532	54
Net (decrease) increase in cash and cash equivalents	(8,836)	20,365
Cash and cash equivalents at the beginning of the period	31,055	33,207
Cash and cash equivalents at the end of the period	$ 22,219	$ 53,572

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

Table of Contents

ORTHFIX INTERNATIONAL N.V.

Notes to the Unaudited Condensed Consolidated Financial Statements

1. Summary of significant accounting policies

(a) Basis of presentation

The accompanying Unaudited Condensed Consolidated Financial Statements have been prepared in accordance with 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 nine months ended September 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 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.

(e) Goodwill

The Company generally calculates fair value of indefinite-lived intangible assets as the present value of estimated future cash flows. In determining the estimated future cash flows associated with intangible assets, the Company uses estimates and assumptions about future revenue contributions, cost structures and remaining useful lives of the asset (asset group). The use of alternative assumptions, including estimated cash flows, discount rates, and alternative estimated remaining useful lives could result in different calculations of impairment.

The Company tests goodwill at least annually for impairment. The Company tests more frequently if indicators are present or changes in circumstances suggest that impairment may exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. The Company assesses goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a reporting unit.

In order to calculate the respective carrying values, the Company initially recorded goodwill based on the purchase price allocation performed at the time of acquisition. Corporate assets and liabilities that directly relate to a reporting unit s operations are ascribed directly to that reporting unit. Corporate assets and liabilities that are not directly related to a specific reporting unit, but from which the reporting unit benefits, are allocated based on the respective contribution measure of each reporting unit. Effective July 1, 2013, the Company re-aligned its segments and consequently reallocated the carrying value of goodwill from its previous reporting units to its new reporting units based on the relative fair value of each new reporting unit to total enterprise value at July 1, 2013.

In the first quarter of 2012, ASU 2011-08, Testing of Goodwill for Impairment became effective. ASU 2011-08 allows entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of a reporting unit (i.e. the first step of the goodwill impairment test). If entities determine, on the basis of qualitative factors, that the fair value of the reporting unit is more likely than not greater than the carrying amount, a quantitative calculation would not be needed.

Table of Contents

As a result of the Company s change in reportable segments, the Company allocated goodwill to each reportable segment, and subsequently evaluated the Spine Fixation and Extremity Fixation reportable units for the possible impairment of goodwill under step two, as there were indicators of impairment when completing step one. The result of this step two analysis was a full impairment of the goodwill allocated to our Spine Fixation and our Extremity Fixation reportable units, totaling $19.2 million. See Note 5, Goodwill for details.

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 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.

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 nine months ended September 30, 2012: decreased net sales by $6.9 million and $20.1 million, respectively; and decreased net income from continuing operations by $2.5 million and $10.3 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

Table of Contents

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 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.

For 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.

Table of Contents

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 nine months ended September 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 period 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.

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 nine months ended September 30, 2012 are summarized in the tables below. The tax effect of the adjustments is estimated based on the Company s effective tax rate.

Table of Contents

	Three Months Ended September 30, 2012						
		Adjustments by Category					
	Previously	Distributor	Inventory			Total	
(U.S. Dollars, in thousands)	Reported	Revenue	Reserves	Royalties	Other	Adjustments	Restated
Net sales	$ 114,752	$ (6,422)	$	$	$ (473)	$ (6,895)	$ 107,857
Cost of sales	22,373	(265)	123	2,018	135	2,011	24,384
Gross profit	92,379	(6,157)	(123)	(2,018)	(608)	(8,906)	83,473
Operating expenses							
Sales and marketing	49,298	(4,212)		(2,018)	(46)	(6,276)	43,022
General and administrative	13,850						13,850
Research and development	6,858						6,858
Amortization of intangibles assets	515				50	50	565
Charges related to U.S. Government resolutions	325				48	48	373
	70,846	(4,212)		(2,018)	52	(6,178)	64,668
Operating income	21,533	(1,945)	(123)		(660)	(2,728)	18,805
Other income and (expense)	(1,485)						(1,485)
Income before income taxes	20,048	(1,945)	(123)		(660)	(2,728)	17,320
Income tax (expense)	(6,930)	131	8		45	184	(6,746)
Net income from continuing operations, net of tax	$ 13,118	$ (1,814)	$ (115)	$	$ (615)	$ (2,544)	$ 10,574

	Nine Months Ended September 30, 2012						
		Adjustments by Category					
	Previously	Distributor	Inventory			Total	
(U.S. Dollars, in thousands)	Reported	Revenue	Reserves	Royalties	Other	Adjustments	Restated
Net sales	$ 350,286	$ (19,678)	$	$	$ (392)	$ (20,070)	$ 330,216
Cost of sales	67,989	(3,837)	2,791	6,223	143	5,320	73,309
Gross profit	282,297	(15,841)	(2,791)	(6,223)	(535)	(25,390)	256,907
Operating expenses							
Sales and marketing	148,629	(5,156)		(6,223)	(25)	(11,404)	137,225
General and administrative	42,715						42,715
Research and development	23,160						23,160
Amortization of intangibles assets	1,575				150	150	1,725
Charges related to U.S. Government resolutions	1,689				(630)	(630)	1,059
	217,768	(5,156)		(6,223)	(505)	(11,884)	205,884
Operating income	64,529	(10,685)	(2,791)		(30)	(13,506)	51,023

Other income and (expense)	(4,942)						(4,942)
Income before income taxes	59,587	(10,685)	(2,791)		(30)	(13,506)	46,081
Income tax (expense)	(20,286)	2,340	1,111		(205)	3,246	(17,040)
Net income from continuing operations, net of tax	$ 39,301	$ (8,345)	$ (1,680)	$	$ (235)	$ (10,260)	$ 29,041

12

Table of Contents

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

	As of December 31, 2012		
(Unaudited, U.S. Dollars, in thousands, except share data)	Previously Reported	Adjustments	Restated
Assets			
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
Total current assets	340,444	(29,861)	310,583
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
Total assets	$ 504,281	$ (31,384)	$ 472,897
Liabilities and shareholders equity			
Current liabilities:			
Trade accounts payable	$ 21,812	763	$ 22,575
Other current liabilities	46,985	(7,375)	39,610
Total current liabilities	68,797	(6,612)	62,185
Long-term debt	20,000		20,000
Deferred income taxes	11,456		11,456
Other long-term liabilities	4,930	6,494	11,424
Total liabilities	105,183	(118)	105,065
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
Total shareholders equity	399,098	(31,266)	367,832

Total liabilities and shareholders equity	$ 504,281	$ (31,384)	$ 472,897

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 September 30, 2012 are as follows:

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended September 30, 2012		
	Previously Reported	Adjustments	Restated
Product sales	$ 103,111	$ (6,559)	$ 96,552
Marketing service fees	11,641	(336)	11,305
Net sales	114,752	(6,895)	107,857
Cost of sales	22,373	2,011	24,384
Gross profit	92,379	(8,906)	83,473
Operating expenses			
Sales and marketing	49,298	(6,276)	43,022
General and administrative	13,850		13,850
Research and development	6,858		6,858
Amortization of intangible assets	515	50	565
Impairment of goodwill			
Charges related to U.S. Government resolutions	325	48	373
	70,846	(6,178)	64,668
Operating income	21,533	(2,728)	18,805
Other income and expense			
Interest expense, net	(464)		(464)
Other expense	(1,021)		(1,021)
	(1,485)		(1,485)
Income before income taxes	20,048	(2,728)	17,320
Income tax expense	(6,930)	184	(6,746)
Net income from continuing operations, net of tax	13,118	(2,544)	10,574
Discontinued operations (Note 15)			
Gain on sale of Breg, Inc., net of tax	221		221
Loss from discontinued operations	(9,046)	(2)	(9,048)
Income tax benefit	3,267	2	3,269
Net loss from discontinued operations, net of tax	(5,558)		(5,558)
Net income	$ 7,560	$ (2,544)	$ 5,016
Net income (loss) per common share-basic:			

Net income from continuing operations, net of tax	$ 0.69	$ (0.14)	$ 0.55
Net loss from discontinued operations, net of tax	(0.29)		(0.29)
Net income per common share-basic	$ 0.40	$ (0.14)	$ 0.26
Net income (loss) per common share-diluted:			
Net income from continuing operations, net of tax	$ 0.67	$ (0.13)	$ 0.54
Net loss from discontinued operations, net of tax	(0.28)	(0.01)	(0.29)
Net income per common share-diluted	$ 0.39	$ (0.14)	$ 0.25
Weighted average number of common shares:			
Basic	19,078,590		19,078,590
Diluted	19,533,021		19,533,021
Comprehensive income	$ 9,067	$ (2,627)	$ 6,440

14

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

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Nine Months Ended September 30, 2012		
	Previously Reported	Adjustments	Restated
Product sales	$ 315,837	$ (19,775)	$ 296,062
Marketing service fees	34,449	(295)	34,154
Net sales	350,286	(20,070)	330,216
Cost of sales	67,989	5,320	73,309
Gross profit	282,297	(25,390)	256,907
Operating expenses			
Sales and marketing	148,629	(11,404)	137,225
General and administrative	42,715		42,715
Research and development	23,160		23,160
Amortization of intangible assets	1,575	150	1,725
Impairment of goodwill			
Charges related to U.S. Government resolutions	1,689	(630)	1,059
	217,768	(11,884)	205,884
Operating income	64,529	(13,506)	51,023
Other income and expense			
Interest expense, net	(3,950)		(3,950)
Other expense	(992)		(992)
	(4,942)		(4,942)
Income before income taxes	59,587	(13,506)	46,081
Income tax expense	(20,286)	3,246	(17,040)
Net income from continuing operations, net of tax	39,301	(10,260)	29,041
Discontinued operations (Note 15)			
Gain on sale of Breg, Inc., net of tax	1,261		1,261
Loss from discontinued operations	(15,398)	1,024	(14,374)
Income tax benefit	5,617	132	5,749
Net loss from discontinued operations, net of tax	(8,520)	1,156	(7,364)
Net income	$ 30,781	$ (9,104)	$ 21,677
Net income (loss) per common share-basic:			

Net income from continuing operations, net of tax	$ 2.08	$ (0.54)	$ 1.54
Net loss from discontinued operations, net of tax	(0.45)	0.06	(0.39)
Net income per common share-basic	$ 1.63	$ (0.48)	$ 1.15
Net income (loss) per common share-diluted:			
Net income from continuing operations, net of tax	$ 2.04	$ (0.53)	$ 1.51
Net loss from discontinued operations, net of tax	(0.45)	0.07	(0.38)
Net income per common share-diluted	$ 1.59	$ (0.46)	$ 1.13
Weighted average number of common shares:			
Basic	18,861,374		18,861,374
Diluted	19,300,263		19,300,263
Comprehensive income	$ 30,615	$ (8,657)	$ 20,751

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 the FIFO method, 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 sales 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 sales are recognized.

Inventories, net of reserves, were as follows:

(US$ in thousands)	September 30, 2013	December 31, 2012 (Restated)
Raw materials	$ 6,038	$ 7,623
Work-in-process	8,230	7,886
Finished products	40,682	28,308
Field inventory	31,682	22,629
Consignment inventory	4,589	6,155
Deferred cost of sales	8,983	10,772
Total Inventory	$ 100,204	$ 83,373

4. Patents and other intangible assets

(US$ in thousands)	September 30, 2013	December 31, 2012 (Restated)
Cost		
Patents	$ 41,135	$ 38,905
Trademarks definite lived	632	657
	41,767	39,562
Accumulated amortization		
Patents	(31,487)	(31,845)
Trademarks definite lived	(459)	(427)

		(31,946)		(32,272)
Patents and other intangible assets, net	$	9,821	$	7,290

16

Table of Contents

5. Goodwill

The following table presents the changes in the net carrying value of goodwill by reportable segment as well as the reallocation and impairment of goodwill as of July 1, 2013 in conjunction with our change in reportable segments. (See Note 1 Summary of significant accounting policies):

(US$ in thousands)	Spine	Orthopedics	BioStim	Biologics	Spine Fixation	Extremity Fixation	Total
At December 31, 2011	$ 41,419	$ 31,675	$	$	$	$	$ 73,094
Foreign currency	145	1,149					1,294
At December 31, 2012	41,564	32,824					74,388
Foreign currency	(163)	(1,467)					(1,630)
At June 30, 2013	41,401	31,357					72,758
Reallocation at July 1, 2013	(41,401)	(31,357)	42,678	10,887	9,368	9,825	
Impairment					(9,368)	(9,825)	(19,193)
Foreign currency			1,472	368			1,840
At September 30, 2013	$	$	$ 44,150	$ 11,255	$	$	$ 55,405

Goodwill Impairment

The Company tests goodwill at least annually for impairment. The Company tests more frequently if indicators are present or changes in circumstances suggest that impairment may exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. The Company assesses goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a reporting unit.

In order to calculate the respective carrying values, the Company initially recorded goodwill based on the purchase price allocation performed at the time of acquisition. Corporate assets and liabilities that directly relate to a reporting unit s operations are ascribed directly to that reporting unit. Corporate assets and liabilities that are not directly related to a specific reporting unit, but from which the reporting unit benefits, are allocated based on the respective contribution measure of each reporting unit. Effective July 1, 2013, the Company re-aligned its segments, and consequently reallocated the carrying value of goodwill to its new reporting units, determined to be the Company s segments (i.e., BioStim, Biologics, Spine Fixation, and Extremity Fixation), based on the relative fair value of each new reporting unit to total enterprise value at July 1, 2013.

As a result of the Company s change in reportable segments, the Company re-allocated goodwill to each reporting unit. We estimated the fair value of each reporting unit using a weighting of fair values derived from an income approach, a cost approach, and a market approach (all Level 3 fair value measurements). Under the income approach, we calculated the fair value of each reporting unit based on the present value of its estimated future cash flows. Cash flow projections are based on our estimates of revenue growth rates and operating margins, taking into consideration

industry and market conditions. The discount rate used was based on the weighted average cost of capital adjusted for the risks associated with the reporting unit and the projected cash flows. The cost approach involves methods of determining a Company s value by analyzing the market value of a Company s assets. The market approach estimates fair value based on market multiples of revenue and earnings of comparable publicly traded companies that have similar operating and investment characteristics as our online reporting unit.

Upon estimating the fair value of the reporting units, we determined it was less than its carrying value for two of our reporting units, Spine Fixation and Extremity Fixation. As a result, we performed step two of the impairment analysis and allocated the fair value of these reporting units to the estimated fair values of each of the assets and liabilities of the reporting units (including identifiable intangible assets) with the excess fair value being the implied goodwill. Estimating the fair value of certain assets and liabilities requires significant judgment about future cash flows. The implied fair value of the reporting unit s goodwill was less than its carrying value, which we recorded as a full impairment loss of goodwill for our Spine Fixation and Extremity Fixation reporting units, totaling $19.2 million, during the third quarter of 2013.

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 September 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 ($7.8 million) and 5.8 million ($7.6 million) at September 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 Sale of Breg and Disposition of Sports Medicine SBU) 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 September 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 September 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 September 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, as a result of the delay in filing our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 and expected delay in filing this Report, 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. The Company was in compliance with the affirmative and negative covenants at September 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 September 30, 2013 and December 31, 2012 is $200.5 million and $213.4 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities from access to cash held by Orthofix Holdings, Inc. and its subsidiaries. All of the Company s subsidiaries that are parties to the Credit Agreement have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of September 30, 2013 and December 31, 2012 was $22.7 million and $21.3 million, respectively.

In conjunction with obtaining the Credit Facilities and the Credit Agreement, as amended, the Company incurred debt issuance costs of $5 million. These costs are being amortized using the effective interest method over the life of the Credit Facilities. In conjunction with the Term Loan Facility repayment in May 2012, the Company wrote off $0.8 million of related debt issuance costs. As of September 30, 2013 and December 31, 2012, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were $1.3 million and $1.8 million, respectively.

Table of Contents

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 September 30, 2013	Fair value: favorable (unfavorable)	Balance sheet location
Cross-currency swap	$ (523)	Other long-term liabilities
As of December 31, 2012		
Cross-currency swap	$ 305	Other long-term assets

(US$ in thousands)	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Cross-currency swap unrealized gain (loss) recorded in other comprehensive income (loss), net of taxes	$ 582	$ 253	$ 486	$ 177

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 September 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 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.

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.

Table of Contents

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

(US$ in thousands)	Balance September 30, 2013	Level 1	Level 2	Level 3
Derivative financial instruments (1)				
Cash flow hedges				
Cross-currency swap liability	$ (523)	$	$ (523)	$

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

(1) See Note 8, Derivative Instruments

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	$ 4,614	$ 131	$ 4,745
Unrealized gain on cross-currency swap, net of tax of $275		486	486
Foreign currency translation adjustment (1)	(273)		(273)
Balance at September 30, 2013	$ 4,341	$ 617	$ 4,958

(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:

(US$ in thousands)	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012 (Restated)	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012 (Restated)
Net income (loss)	$ (19,822)	$ 5,016	$ (17,639)	$ 21,677
Other comprehensive income (loss):				
Unrealized gain (loss) on cross-currency swap, net of tax of $275	582	253	486	177
Foreign currency translation adjustment	3,176	1,171	(273)	215
Total comprehensive income (loss)	$ (16,064)	$ 6,440	$ (17,426)	$ 22,069

11. Earnings per share

For the three and nine months ended September 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 nine months ended September 30, 2013, potentially dilutive shares totaled 176,482. The following is a reconciliation of the weighted average shares used in the basic and diluted net income (loss) per common share computations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Weighted average common shares-basic	18,142,935	19,078,590	18,897,887	18,861,374
Effect of dilutive securities:				
Unexercised stock options net of treasury share repurchase		454,431		438,889
Weighted average common shares-diluted	18,142,935	19,533,021	18,897,887	19,300,263

20

Options to purchase shares of common stock with exercise prices in excess of the average market price of common shares are not included in the computation of diluted earnings per share. There were 1,647,878 and 1,186,259 outstanding options not included in the diluted earnings per share computation for the three and nine months ended September 30, 2013, respectively, because the inclusion of these options was antidilutive. There were 636,900 and 688,636 outstanding options not included, respectively, in the diluted earnings per share computation for the three and nine months ended September 30, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(US$ in thousands)	**2013**	**2012**	**2013**	**2012**
Cost of sales	$ 27	$ 155	$ (249)	$ 438
Sales and marketing	469	598	1,375	1,440
General and administrative	726	1,309	3,431	2,851
Research and development	55	34	157	105
Total	$ 1,277	$ 2,096	$ 4,714	$ 4,834

For the nine months ended September 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 three and nine months ended September 30, 2013, there were 56,281 and 199,725 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the three and nine months ended September 30, 2012, there were 332,985 and 814,022 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 $8.1 million and $17.0 million provision for income tax which reflects an effective tax rate of 456.0% and 37.5% on pre-tax loss for the nine months ended September 30, 2013 and pre-tax income for the nine months ended September 30, 2012. For the nine months ended September 30, 2012, $0.6 million of income related to legal settlements is discrete and not included in the foregoing calculation of the effective tax rate. Due to the significant variations in the customary relationship between income tax expense and pretax earnings resulting from extraordinary permanent items, the company provided for income taxes on a year to date basis for the nine months ended September 30, 2013. The principal factors affecting the Company s effective tax rate was the company s mix of

earnings amongst various tax jurisdiction, state taxes, and permanent items related to the $19.2 million goodwill impairment in the current quarter.

Excluding the impact of various discrete charges, the effective tax rate on continuing operations for the first nine months of 2012 was 38.8%. 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 September 30, 2013 and December 31, 2012, the Company s gross unrecognized tax benefit was $0.7 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 September 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 $292.0 million at December 31, 2012. The $292.0 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

On July 1, 2013, we began certain organizational and executive leadership changes to align with how our Chief Operating Decision Maker (the CODM) reviews performance and makes decisions in managing the Company. We manage our business by our four strategic business units (SBUs), which are comprised of BioStim, Biologics, Spine Fixation, and Extremity Fixation supported by Corporate activities. These SBUs represent the segments for which our CODM reviews financial information and makes resource allocation decisions among business units. The primary metric used by the Chief Operating Decision Maker in managing the Company is net margin, which is defined as gross profit less sales and marketing expense. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. Accordingly, our segment information has been prepared based on our four SBUs reporting segments. These four segments are discussed below.

BioStim

The BioStim Strategic Business Unit manufactures, distributes, and provides support services for a portfolio of market leading devices for enhancing bone fusion that utilize Orthofix s patented pulsed electromagnetic (PEMF) technology. These Food and Drug Administration-approved Class 3 medical devices are indicated as an adjunctive treatment to enhance fusion success in cervical and lumbar spine as well as a therapeutic treatment for non-healing fractures outside of the spine (non-unions). The PEMF technology is supported by a strong clinical background on mechanism of action in the scientific literature and current research and clinical studies are underway to identify potential new clinical indications.

Biologics

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

Spine Fixation

The Spine Fixation strategic business unit specializes in the design, development and marketing of a portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products through a network of distributors and affiliates. This strategic business unit uses distributor sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.

Extremity Fixation

Extremity Fixation offers products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This strategic business unit specializes in the design, development, and marketing of the

Company s orthopedic products used in fracture repair, deformity correction and bone reconstruction. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates. This strategic business units uses both direct and distributor sales representatives to sell orthopedics products to hospitals, doctors, and other health providers, globally.

Corporate

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

The accounting policies of the segments are the same as those described in the business segment information found in Note 13, Business segment information to the Consolidated Financial Statements included in the 2012 Form 10-K/A.

22

Table of Contents

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

	External Net Sales by SBU Three Months Ended September 30,			
(US$ in thousands)	2013	2012 (Restated)	Reported Growth (Restated)	Constant Currency Growth (Restated)
BioStim	$ 31,604	$ 42,310	(25)%	(28)%
Biologics	13,212	12,951	2 %	2 %
Spine Fixation	23,221	25,001	(7)%	(7)%
Extremity Fixation	24,701	27,595	(10)%	(9)%
Total Net Sales	$ 92,738	$ 107,857	(14)%	(15)%

	External Net Sales by SBU Nine Months Ended September 30,			
(US$ in thousands)	2013	2012 (Restated)	Reported Growth (Restated)	Constant Currency Growth (Restated)
BioStim	$ 108,445	$ 134,741	(20)%	(20)%
Biologics	39,827	39,792	%	%
Spine Fixation	71,994	72,972	(1)%	(1)%
Extremity Fixation	74,125	82,711	(10)%	(8)%
Total Net Sales	$ 294,391	$ 330,216	(11)%	(11)%

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

Net margin by SBU (US$ in thousands)	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012 (Restated)	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012 (Restated)
Net margin:				
BioStim	$ 10,614	$ 19,367	$ 45,911	$ 66,354
Biologics	6,743	5,664	18,472	16,524
Spine Fixation	1,227	4,693	7,489	13,379
Extremity Fixation	8,321	11,145	21,766	24,508

Corporate	(469)	(418)	(1,376)	(1,083)
Total net margin	26,436	40,451	92,262	119,682
General and administrative	13,202	13,850	46,736	42,715
Research and development	6,361	6,858	20,653	23,160
Amortization of intangible assets	616	565	1,725	1,725
Costs related to the accounting review and restatement	2,664		2,664	
Impairment of goodwill	19,193		19,193	
Charges related to U.S. Government resolutions		373		1,059
Operating income (loss)	$ (15,600)	$ 18,805	$ 1,291	$ 51,023

Table of Contents

15. Sale of Breg and Disposition of Sports Medicine SBU

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 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, Contingencies .) 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 SBU, 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 $1.1 million and $1.6 million as of September 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 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 nine months ended September 30, 2013 is $3.1 million and $15.8 million, respectively, of expense related to the Company s indemnification of certain specified matters described above.

The Company s condensed consolidated financial statements and related footnote disclosures reflect the Sports Medicine SBU as discontinued operations. Income (loss) associated with the Sports Medicine SBU, 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.

Table of Contents

17. Stock Repurchase Program

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 September 30, 2013, the Company made total repurchases in an amount equal to $12.6 million. The Company has not made any further purchases between September 30, 2013 and the date of this Form 10-Q. To date, the Company has made total repurchases in an amount equal to $39.5 million.

18. Subsequent Event

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 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 condensed consolidated financial statements included herein, which have been prepared in accordance with US GAAP, for the three and nine months ended September 30, 2013 compared to the three and nine months ended September 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 nine months ended September 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 nine months ended September 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 nine months ended September 30, 2012. See Note 2 to our 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 the Company 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 rights for sales to distributors with respect to certain transactions), including some with which certain senior-level personnel were involved, (ii) that at the time of some sales collection was not reasonably assured, and (iii) that certain amounts previously characterized as commissions were paid to related parties of the applicable customer.

The Company assessed the information derived from the Independent Review in making determinations with respect to accounting adjustments reflected in the restated consolidated financial statements contained in 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.

Business Segments

Our segment information is prepared on the same basis that management reviews the financial information for operational decision making purposes. We manage our business by our four strategic business units (SBUs), which are comprised of BioStim, Biologics, Spine Fixation, and Extremity Fixation supported by Corporate activities. These SBUs represent the segments for which our Chief Operating Decision Maker (the CODM) reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information has been prepared based on our four SBUs reporting segments. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. These four segments are discussed below.

BioStim

The BioStim Strategic Business Unit manufactures, distributes, and provides support services for a portfolio of market leading devices for enhancing bone fusion that utilize Orthofix s patented pulsed electromagnetic (PEMF) technology. These Food and Drug Administration-approved Class 3 medical devices are indicated as an adjunctive treatment to enhance fusion success in cervical and lumbar spine as well as a therapeutic treatment for non-healing fractures outside of the spine (non-unions). The PEMF technology is supported by a strong clinical background on mechanism of action in the scientific literature and current research and clinical studies are underway to identify potential new clinical indications.

Biologics

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

Spine Fixation

The Spine Fixation strategic business unit specializes in the design, development and marketing of a portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products through a network of distributors and affiliates. This strategic business unit uses distributor sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.

Extremity Fixation

Extremity Fixation offers products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This strategic business unit specializes in the design, development, and marketing of the

Company s orthopedic products used in fracture repair, deformity correction and bone reconstruction. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates. This strategic business units uses both direct and distributor sales representatives to sell orthopedics products to hospitals, doctors, and other health providers, globally.

Extremity Fixation

Extremity Fixation offers innovative and minimally invasive products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This SBU specializes in the design, development, and marketing of orthopedic repair products. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates. This SBU uses both direct and distributor sales representatives to sell orthopedics products to hospitals, doctors, and other health providers, globally.

Corporate

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

Table of Contents

SBU Revenues

The following table displays net sales by SBU for the three and nine months ended September 30, 2013 and 2012.

The table below presents external net sales by SBU reporting segment (amounts reported for prior periods have been reclassified to conform to our new segment reporting structure):

	External Net Sales by SBU Three Months Ended September 30,			
(US$ in thousands)	2013	2012 (Restated)	Reported Growth (Restated)	Constant Currency Growth (Restated)
BioStim	$ 31,604	$ 42,310	(25)%	(28)%
Biologics	13,212	12,951	2 %	2 %
Spine Fixation	23,221	25,001	(7)%	(7)%
Extremity Fixation	24,701	27,595	(10)%	(9)%
Total Net Sales	$ 92,738	$ 107,857	(14)%	(15)%

	External Net Sales by SBU Nine Months Ended September 30,			
(US$ in thousands)	2013	2012 (Restated)	Reported Growth (Restated)	Constant Currency Growth (Restated)
BioStim	$ 108,445	$ 134,741	(20)%	(20)%
Biologics	39,827	39,792	%	%
Spine Fixation	71,994	72,972	(1)%	(1)%
Extremity Fixation	74,125	82,711	(10)%	(8)%
Total Net Sales	$ 294,391	$ 330,216	(11)%	(11)%

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 September 30,		Nine Months Ended September 30,	
	2013 (%)	2012 (%) (Restated)	2013 (%)	2012 (%) (Restated)
Net sales	100	100	100	100
Cost of sales	26	23	24	22

Gross profit	74	77	76	78
Operating expenses:				
Sales and marketing	46	40	45	41
General and administrative	17	13	17	13
Research and development	7	6	7	7
Amortization of intangible assets		1		1
Costs related to the accounting review and restatement	3		1	
Impairment of goodwill	21		7	
Charges related to U.S. Government inquiries				
Operating income (loss)	(17)	17		16
Net income (loss)	(21)	5	(6)	7

Three Months Ended September 30, 2013 Compared to Three Months Ended September 30, 2012

Net sales decreased $15.2 million to $92.7 million in the third quarter of 2013 compared to $107.9 million for the same period last year. The impact of foreign currency decreased sales by $0.9 million during the third quarter of 2013 when compared to the third quarter of 2012.

Sales

Net sales in our BioStim SBU decreased 25.3% to $31.6 million in the third quarter of 2013 compared to $42.3 million for the same period in the prior year, a decrease of $10.7 million. The decrease in BioStim revenue was primarily attributable to an approximately $6 million reduction in third-party payor revenue driven by our transition to recognize revenue upon accumulation of the full billable package for third party payors given the increased complexity in insurance billing requirements.

Net sales in our Biologics SBU increased $0.2 million or 2.0% to $13.2 in the third quarter of 2013 compared to $13.0 million for the same period in the prior year, driven primarily by an increase in our marketing service fee revenue from the Musculoskeletal Transplant Foundation (MTF) related to the launch of our new tissue form Trinity ELITE This increase was offset by a reduction in our marketing service fee from 70% to 65% which became effective April 1, 2013.

Table of Contents

Net sales in our Spine Fixation SBU decreased $1.8 million to $23.2 million in the third quarter of 2013 compared to $25.0 million for the same period last year, primarily due to a decline in our average selling prices due to price discounting.

Net sales in our Extremity Fixation SBU decreased $2.9 million, to $24.7 million in the third quarter of 2013 compared to $27.6 million for the same period last year. Historically, for most distributor transactions within our Extremity Fixation SBU, 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 Extremity Fixation GBU on a prospective basis beginning on April 1, 2013 which caused the majority of the decrease in net sales in the third quarter of 2013 compared to the third quarter of 2012.

Gross Profit Our gross profit decreased $14.7 million to $68.8 million in the third quarter of 2013 compared to $83.5 million for the same period last year. Gross profit as a percent of net sales in the third quarter of 2013 was 74.2% for the third quarter of 2013 and 77.4% for 2012 during the same period. This decrease is due to the decrease of sales in our BioStim SBU which carry a higher gross margin compared to our other products and the decline in average selling prices in our Spine Fixation SBU.

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 $0.6 million, to $42.4 million in the third quarter of 2013 compared to $43.0 million in the third quarter of 2012. As a percent of net sales, sales and marketing expense was 45.7% and 39.9% in the third 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 third quarter of 2013 compared to the third quarter of 2012.

General and Administrative Expense General and administrative expense decreased $0.7 million, or 6.1%, in the third quarter of 2013 to $13.2 million compared to $13.9 million in the third quarter of 2012. General and administrative expense as a percent of net sales was 14.2% in the third quarter of 2013 compared to 12.8% for the same period last year. This increase as a percent of sales was driven primarily by the impact of lower sales on non-variable general and administrative expenses.

Research and Development Expense Research and development expense decreased $0.5 million in the third quarter of 2013 to $6.4 million compared to $6.9 million in the third quarter of 2012. As a percent of net sales, research and development expense was 6.9% in the third quarter of 2013 compared to 6.4% for the same period last year.

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

Costs related to the accounting review and restatement As part of our accounting review and restatement of our consolidated financial statements (see Note 2), the Company incurred $2.7 million of charges related to these activities in the third quarter of 2013.

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

Charges Related to U.S. Government Resolutions The Company recorded no charge in the third quarter of 2013 but 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 $0.6 million for the third quarter of 2013 compared to $0.5 million for the same period last year.

Other Income and Expense Other expense was $1.5 million and $1.0 million for the third 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 (2.5)% and 39.5% during the third quarters of 2013 and 2012, respectively. For the three months ended September 30, 2012, $0.2 million of income related to legal settlements is discrete and not included in the foregoing calculation of the effective tax rate. Due to the significant variations in the customary relationship between income tax expense and pretax earnings resulting from extraordinary permanent items, the company provided for income taxes on a year to date basis for the three months ended September 30, 2013. The principal factors affecting the Company s effective tax rate was the company s mix of earnings amongst various tax jurisdiction, state taxes, and permanent items related to the $19.2 million goodwill impairment in the current quarter.

Discontinued operations Discontinued operations include approximately $1.7 million and $5.6 million in the third quarter of 2013 and 2012, respectively, 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.

Net Income (loss) Net income (loss) for the third quarter of 2013 was a net loss of $(19.8) million, or $(1.10) per basic and diluted share, compared to net income of $5.0 million, or $0.26 per basic share and $0.25 diluted share for the same period last year.

Table of Contents

Nine Months Ended September 30, 2013 Compared to Nine Months Ended September 30, 2012

Net sales decreased $35.8 million to $294.4 million in the first nine months of 2013 compared to $330.2 million for the same period last year. The impact of foreign currency decreased sales by $.2 million during the first nine months of 2013 when compared to the same period of 2012.

Sales

Net sales in our BioStim SBU decreased 20% to $108.4 million in the nine months ended September 30, 2013 compared to $134.7 million for the same period in the prior year, a decrease of $26.3 million. The decrease in BioStim revenue was primarily attributable to a decline in sales of our stimulation products for spine and cervical application caused by distribution turnover and changes in certain payors policies. The decrease for the nine months ended September 30, 2013 was also negatively impacted by a reduction in third-party payor revenue driven by our transition in third quarter of 2013 to recognize revenue upon accumulation of the full billable package for the third party payors given the increased complexity in insurance billing requirements.

Net sales in our Biologics SBU remained flat at $39.8 million in the nine months ended September 30, 2013 and the nine months ended September 30, 2012. Increases in net sales of Spinal Regenerative Biologics products of $0.3 million compared to the prior year were primarily offset by decreases in net sales of Orthopedic Regenerative Biologics products of $0.2 million.

Net sales in our Spine Fixation SBU remained relatively flat, decreasing $1.0 million to $72.0 million in the nine months ended September 30, 2013 compared to $73.0 million for the same period in the prior year.

Net sales in our Extremity Fixation SBU decreased 10.4% to $74.1 million in the nine month period ended September 30, 2013 compared to $82.7 million for the same period last year, a decrease of $8.6 million. Historically, for most distributor transactions within our Extremity Fixation SBU, 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 Extremity Fixation GBU on a prospective basis beginning on April 1, 2013 which caused the majority of the decrease in net sales in the first nine months of 2013 compared to the first nine months of 2012.

Gross Profit Our gross profit decreased $32.3 million to $224.6 million in the first nine months of 2013, compared to $256.9 million for the same period last year. Gross profit as a percent of net sales in the first nine months of 2013 was 76.3% for the first nine months of 2013 and 77.8% in 2012 during the same period.

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 $4.9 million, to $132.3 million in the first nine months of 2013 compared to $137.2 million in the first nine months of 2012. As a percent of net sales, sales and marketing expense was 45% and 41.6% in the first nine months of 2013 and 2012, respectively.

General and Administrative Expense General and administrative expense increased $4.0 million, or 9.4%, in the first nine months of 2013 to $46.7 million compared to $42.7 million in the first nine months of 2012. General and administrative expense as a percent of net sales was 15.9% in the first nine months of 2013 compared to 12.9% 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 $2.5 million in the first nine months of 2013 to $20.7 million compared to $23.2 million for the same period last year. As a percent of net sales, research and development expense was 7.0% in the first nine months of 2013 and 2012. The decrease in research and development expenses in the first nine 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 $1.0 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 $2.0 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 $1.7 million in the first nine months of 2013 compared to $1.7 million for the same period in 2012.

Costs related to the accounting review and restatement As part of our accounting review and restatement of our consolidated financial statements (see Note 2), the Company incurred $2.7 million, of charges related to these activities in the first nine months of 2013.

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

Charges Related to U.S. Government Resolutions The Company recorded no charge in the first nine months of 2013 but a $1.1 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 $1.6 million for the first nine months of 2013 compared to $4.0 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 was $2.1 million for the first nine months of 2013 and $1 million of expense for 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 456.0% and 37.5% during the first nine months of 2013 and 2012, respectively. For the nine months ended September 30, 2012, $0.6 million of income related to legal settlements is discrete and not included in the foregoing calculation of the effective tax rate. Due to the significant variations in the customary relationship between income tax expense and pretax earnings resulting from extraordinary permanent items, the company provided for income taxes on a year to date basis for the nine months ended September 30, 2013. The principal factors affecting the Company s effective tax rate was the company s mix of earnings amongst various tax jurisdiction, state taxes, and permanent items related to the $19.2 million goodwill impairment in the current quarter.

Discontinued operations Discontinued operations include approximately $11.3 million and $7.4 million in the first nine months of 2013 and 2012, respectively, 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 nine months of 2012 also includes the results of our Sports Medicine SBU up to May 24, 2012 (the closing date of the sale of Breg), net of income taxes and the gain on the sale of Breg, of $1.3 million, net of income taxes.

Net Income (loss) Net income (loss) for the first nine months of 2013 was a loss of $(17.6) million or $(0.94) per basic and diluted share, compared to net income of $21.7 million, or $1.15, per basic share and $1.13 per diluted share for the same period last year.

Liquidity and Capital Resources

Cash and cash equivalents including Restricted Cash at September 30, 2013 were $45.0 million, of which $22.7 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 December 31, 2012, of which $21.3 million was subject to certain restrictions under the senior secured credit agreement discussed below.

Net cash provided by operating activities was $52.0 million and $68.4 million for the nine months ended September 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 $39.3 million to a net loss of $17.6 million for the nine months ended September 30, 2013 from a net income of $21.7 million for the comparable period in the prior year. Non-cash items for the nine months ended September 30, 2013 increased $28.5 million to $44.1 million compared to non-cash items of $15.6 million in the same period of 2012. Working capital accounts provided $25.5 million of cash for the nine months ended September 30, 2013 and $31.1 million for the nine months ended September 30, 2012. For the nine months ended September 30, 2012, 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 day s sales in receivables of 75 days at September 30, 2013 and 91 days at September 30, 2012, and inventory turns of 0.9 times as of September 30, 2013 and 1.3 times as of September 30, 2012.

Net cash used by investing activities was $23.0 million for the nine months ended September 30, 2013 compared to net cash provided by investing activities of $135.1 million for the nine months ended September 30, 2012. During the second quarter of 2012, we sold Breg, Inc. for net proceeds of $153.8 million. During the nine months ended September 30, 2013 and 2012, we invested $24.0 million and $18.6 million in capital expenditures, respectively.

Net cash used in financing activities was $37.4 million for the nine months ended September 30, 2013 compared to $183.2 million for the nine months ended September 30, 2012. During the nine months ended September 30, 2013, we made no repayments on our revolving debt as compared to $188.7 million during the nine months ended September 30, 2012. Our restricted cash balance usage decreased $18.8 million from $20.2 million in the nine months ended September 30, 2012 to $1.4 million in the nine months ended September 30, 2013, primarily related to the cash received from the Blackstone escrow fund which was recorded in Restricted Cash in accordance with the credit facility. During the nine months ended September 30, 2013 and 2012, we received proceeds of $3.4 million and $24.4 million, respectively, from the issuance of 199,725 shares and 814,022 shares, respectively, of our common

stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the nine months ended September 30, 2013 we purchased 1,437,758 of our outstanding shares associated with the stock repurchase program for a total of $39.5 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 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, 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 September 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 September 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 September 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 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 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 September 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 September 30, 2013 and December 31, 2012 was $200.5 million and $213.4 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 September 30, 2013 and December 31, 2012 was $22.7 million and $21.3 million, respectively.

At September 30, 2013, we had no outstanding bank borrowings and unused available line of credit of approximately 5.8 million ($7.8 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 September 30, 2013, the Company made total repurchases in an amount equal to $12.6 million. The Company has not made any further purchases between September 30, 2013 and the date of this Form 10-Q. To date, the Company has made total repurchases in an amount equal to $39.5 million.

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 September 30, 2013, we had a currency swap in place to minimize foreign currency exchange risk related to a 28.7 million ($38.8 million translated at the September 30, 2013 foreign exchange rate) intercompany note. As of September 30, 2013 the fair value of the currency swap was approximately $(0.5) million and is recorded in other long-term liabilities.

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 September 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 September 30, 2013, our effective interest rate on our Credit Facilities was 2.7%. Based on the balance outstanding under the Credit Facilities as of September 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.

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 sales 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 September 30, 2013, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million ($31.4 million). We recorded a foreign currency gain during the nine months ended September 30, 2013 of $0.2 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 nine months ended September 30, 2013, we recorded a foreign currency loss of $1.4 million on the statement of operations resulting from gains and losses in foreign currency transactions.

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 September 30, 2013.

Table of Contents

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 September 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 September 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 September 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.

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.

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 September 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

Table of Contents

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 year, subsequent write-ups based on demand are not recognized; and
- 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;

We have established and hired a Director of Controls and Process Improvement, whose primary duties are the design and implementation of internal control over financial reporting;

We have engaged a professional firm to perform testing and evaluation of the Company s internal controls, and to assist the Company in designing and implementing additional financial reporting controls and financial reporting control enhancements; and

We are evaluating our accounting systems to determine appropriate enhancements.

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.

Table of Contents

Changes in Internal Control over Financial Reporting

Other than as described above, there have not been any changes in our internal control over financial reporting during the fiscal quarter ended September 30, 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 1 A . Risk Factors

As of September 30, 2013, there had been no material changes to our risk factors from the factors discussed in Part I, Item 1A., Risk Factors in our Annual Report on Form 10-K/A, as amended, for the fiscal year ended December 31, 2012.

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 nine months ended September 30, 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
June 2013	472,650	$ 27.77	988,515	$ 23,131,669
July 2013	449,063	$ 28.04	1,437,758	$ 10,505,778
Total for period ending September 30, 2013	1,437,578	$ 27.55	1,437,758	$ 10,505,778

Table of Contents

Item 6. Exhibits

10.1	Amendment No. 3 to Matrix Commercialization Collaboration Agreement, entered into on July 1, 2013 and effective as of June 25, 2013, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company s current report on Form 8-K filed July 8, 2013 and incorporated herein by reference).
10.2	Limited Waiver, entered into on August 14, 2013, by and among Orthofix International N.V., Orthofix Holdings, Inc. and certain of its wholly owned subsidiaries, and certain lender parties thereto. (filed as an exhibit to the Company s current report on Form 8-K filed August 19, 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 September 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 25, 2014

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

Date: March 25, 2014

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