ORTHOFIX INTERNATIONAL N V
Form 10-Q
March 25, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 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.

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EXPLANATORY NOTE

Orthofix International N.V. (together with its respective consolidated subsidiaries and affiliates, the Company, sometimes referred to as we , us or our) is filing this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 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.

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Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans anticipates, believes, estimates, projects, intends, predicts, potential or continue or other comparable 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.

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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.

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ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

For the three and nine months ended September 30, 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.

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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.

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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.

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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

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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.

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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.

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	Three Months Ended September 30, 2012						
		Adjustments by Category					
(U.S. Dollars, in thousands)	Previously Reported	Distributor Revenue	Inventory Reserves	Royalties	Other	Total 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					
(U.S. Dollars, in thousands)	Previously Reported	Distributor Revenue	Inventory Reserves	Royalties	Other	Total 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

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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