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

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from __________ to __________.

Commission File Number: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

Curaçao	**Not applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7 Abraham de Veerstraat Curaçao	**Not applicable**
(Address of principal executive offices)	**(Zip Code)**

599-9-4658525

(Registrant s telephone number, including area code)

Not applicable

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

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

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

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

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

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

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

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EXPLANATORY NOTE

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

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

Description of the Further Restatement

The errors corrected by the Further Restatement are as follows:

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

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

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

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

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

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

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

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

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

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Forward-Looking Statements

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

The forward-looking statements in this filing do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to the recent Audit Committee accounting matters review, the restatements of financial statements for certain prior periods described in the Amendments and herein, and related legal proceedings (including potential action by the Division of Enforcement of the SEC and pending securities class action litigation), the Company s review of allegations of improper payments involving the Company s Brazil-based subsidiary, the Company s previous and current non-compliance with certain Nasdaq Stock Market LLC listing rules, and related pending hearings proceedings in connection therewith, the expected sales of products, including recently launched products, unanticipated expenditures, changing relationships with customers, suppliers, strategic partners and lenders, changes to and the interpretation of governmental regulations, the resolution of pending litigation matters (including indemnification obligations with respect to certain product liability claims against, and the government investigation of, the Company s former sports medicine global business unit), ongoing compliance obligations under a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services (and related terms of probation), a deferred prosecution agreement with the U.S. Department of Justice and a consent decree with the SEC, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the spine and orthopedic industries, credit markets and the economy, corporate development and market development activities, including acquisitions or divestitures, and other risks described in Part I, Item 1A under the heading *Risk Factors* in the 2013 Form 10-K/A, as well as in other reports that the Company will file in the future.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Balance Sheets

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

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

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

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ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

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

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

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

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

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ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Cash Flows

For the nine months ended September 30, 2014 and 2013

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

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

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

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ORTHFIX INTERNATIONAL N.V.

Notes to the Unaudited Condensed Consolidated Financial Statements

1. Summary of significant accounting policies

(a) Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures, normally included in financial statements prepared in accordance with U.S. GAAP, have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the nine months ended September 30, 2014, are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. The balance sheet at December 31, 2013, has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. For further information, refer to the consolidated financial statements and notes thereto contained in the 2013 Form 10-K/A. The notes to the unaudited condensed consolidated financial statements are presented on a continuing basis unless otherwise noted.

(b) Reclassifications

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

(c) Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates including those related to contractual allowances, doubtful accounts, inventories, potential intangible assets and goodwill impairment, income taxes, and share based compensation. Actual results could differ from these estimates.

(d) Foreign currency translation

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

(e) Collaborative agreement

The Company receives a marketing fee through collaboration with Musculoskeletal Transplant Foundation (MTF) for Trinity Evolution® and Trinity ELITE®, for which, the Company has exclusive marketing rights, and VersaShield for which we have non-exclusive marketing rights. Under the agreements with MTF, MTF processes the tissues, maintains inventory, and invoices hospitals and surgery centers and other points of care for service fees, which are submitted by customers via purchase orders. MTF is considered the primary obligor in these arrangements and therefore the Company recognizes these marketing service fees on a net basis upon shipment of the product to the customer.

(f) Recently issued accounting standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers. ASU 2014-09 supersedes the revenue recognition requirements in Revenue Recognition (Topic 605), and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. ASU 2014-09 is effective for the Company in the fiscal year beginning on January 1, 2017, including interim periods within that reporting period and is to be applied retrospectively, with early application not permitted. The Company is currently evaluating the effect that adopting this new accounting guidance will have on consolidated results of operations, cash flows and financial position.

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2. Original and Further Restatement of the Consolidated Financial Statements

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

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

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

Background of Further Restatement

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

Co-Pay and Self-Pay Revenue Adjustments

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

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

Bad Debt Timing Adjustments

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

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

Accounts Receivable Reserve Adjustments

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

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

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

Intercompany Profit Adjustments

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

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

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

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

Inventory

Inventory Existence

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

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

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

Inventory Reserves

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

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

Other Adjustments

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

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

		Three Months Ended September 30, 2013 Further Restatement Adjustments by Category							
(U.S. Dollars, in thousands)	Originally Reported in 2013 Form 10-Q	Co-Pay and Self-Pay Revenue	Bad Debt Timing	Accounts Receivable Reserve	Intercompany Profit	Inventory	Other	Total Further Restatement Adjustments	Restated
Net sales	$ 92,738	$ (1,191)	$	$ 240	$	$	$ 19	$ (932)	$ 91,806
Cost of sales	23,920				770	1,320	(946)	1,144	25,064
Gross profit	68,818	(1,191)		240	(770)	(1,320)	965	(2,076)	66,742
Operating expenses									
Sales and marketing	42,382	(1,191)		14			(2,129)	(3,306)	39,076
General and administrative	13,202						(269)	(269)	12,933
Research and development	6,361								6,361
Amortization of intangible assets	616								616
Costs related to the accounting review and restatement	2,664								2,664
Impairment of goodwill	19,193								19,193
	84,418	(1,191)		14			(2,398)	(3,575)	80,843
Operating (loss) income	(15,600)			226	(770)	(1,320)	3,363	1,499	(14,101)
Other income and (expense)	(2,036)						16	16	(2,020)
Loss before income taxes	(17,636)			226	(770)	(1,320)	3,379	1,515	(16,121)
Income tax expense	(448)			(79)	(270)	462	(588)	65	(383)
Net loss from continuing operations	$ (18,084)	$	$	$ 147	$ (500)	$ (850)	$ 2,791	$ 1,580	$ (16,504)

		Nine Months Ended September 30, 2013 Further Restatement Adjustments by Category							
(U.S. Dollars, in thousands)	Originally Reported in 2013 Form 10-Q	Co-Pay and Self-Pay Revenue	Bad Debt Timing	Accounts Receivable Reserve	Intercompany Profit	Inventory	Other	Total Further Restatement Adjustments	Restated
Net sales	$ 294,391	$ (2,980)	$	$ 364	$	$	$ (50)	$ (2,666)	$ 291,725
Cost of sales	69,783				1,012	3,399	(1,405)	3,006	72,789

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

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

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

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

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

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

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

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

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

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

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

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

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3. Inventories

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

Work-in-process and finished products include material, labor and production overhead costs. Deferred cost of sales result from certain transactions where the Company has shipped product or performed services for which all revenue recognition criteria have not been met. Once the revenue recognition criteria have been met, both the deferred revenues and associated cost of sales are recognized.

Inventories were as follows:

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

4. Patents and other intangible assets

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