

ORTHOFIX INTERNATIONAL N V
Form 10-Q
November 02, 2012
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2012

OR

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

For the transition period from to .

Commission File Number: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

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

Curaçao
(State or other jurisdiction of
incorporation or organization)

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

7 Abraham de Veerstraat

Curaçao
(Address of principal executive offices)

Not applicable
(Zip Code)

599-9-4658525

(Registrant's telephone number, including area code)

Not applicable

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

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

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

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

Large Accelerated filer

Accelerated filer

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

Smaller Reporting Company

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

As of October 29, 2012, 19,320,462 shares of common stock were issued and outstanding.

Table of Contents**Table of Contents**

	Page
PART I	
<u>FINANCIAL INFORMATION</u>	3
Item 1.	3
<u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2012 (unaudited) and December 31, 2011</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and 2011 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011 (unaudited)</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
Item 2.	18
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
Item 3.	25
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	25
Item 4.	25
<u>Controls and Procedures</u>	25
PART II	26
<u>OTHER INFORMATION</u>	26
Item 1.	26
<u>Legal Proceedings</u>	26
Item 1A.	26
<u>Risk Factors</u>	26
Item 6.	26
<u>Exhibits</u>	26
<u>SIGNATURES</u>	27

Forward-Looking Statements

This Form 10-Q 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, *potentially*, comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any such statement, or the risk factors described in Item 1A under the heading *Risk Factors*, 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 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 court review and approval of our pending settlement of the government's investigation of our regenerative stimulation business, as well as 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* section of this Form 10-Q), and our ongoing compliance obligations under a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services 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 this Form 10-Q and those set forth in our Annual Statement on Form 10-K, as amended, for the year ended December 31, 2011, under Item 1A, *Risk Factors*.

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, 2012 (unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 53,572	\$ 33,207
Restricted cash	67,319	45,476
Trade accounts receivable, less allowance for doubtful accounts of \$13,381 and \$9,376 at September 30, 2012 and December 31, 2011, respectively	155,978	132,828
Inventories, net	80,822	82,969
Deferred income taxes	19,059	16,349
Escrow receivable		41,537
Prepaid expenses and other current assets	28,122	26,069
Assets held for sale		171,185
Total current assets	404,872	549,620
Property, plant and equipment, net	46,550	43,368
Patents and other intangible assets, net	7,000	8,236
Goodwill	73,952	73,094
Deferred income taxes	19,158	18,584
Other long-term assets	13,541	11,570
Total assets	\$ 565,073	\$ 704,472
Liabilities and shareholders equity		
Current liabilities:		
Bank borrowings	\$ 282	\$ 1,318
Current portion of long-term debt		17,500
Trade accounts payable	18,089	16,488
Accrued charges related to U.S. Government resolutions	76,743	82,500
Other current liabilities	57,349	45,327
Liabilities held for sale		22,676
Total current liabilities	152,463	185,809
Long-term debt	20,000	191,195
Deferred income taxes	9,779	9,778
Other long-term liabilities	5,221	2,519
Total liabilities	187,463	389,301
Contingencies (Note 16)		
Shareholders equity:		
Common shares \$0.10 par value; 50,000,000 shares authorized; 19,279,466 and 18,465,444 issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	1,928	1,846
Additional paid-in capital	246,052	214,310
Retained earnings	128,035	97,254
Accumulated other comprehensive income	1,595	1,761

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

Total shareholders' equity	377,610	315,171
Total liabilities and shareholders' equity	\$ 565,073	\$ 704,472

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****For the three and nine months ended September 30, 2012 and 2011**

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net sales	\$ 114,752	\$ 117,306	\$ 350,286	\$ 347,036
Cost of sales	22,373	23,854	67,989	69,380
Gross profit	92,379	93,452	282,297	277,656
Operating expenses				
Sales and marketing	49,298	49,358	148,629	146,757
General and administrative	13,849	13,976	42,715	50,105
Research and development	6,858	5,982	23,160	17,655
Amortization of intangible assets	515	537	1,575	1,641
Charges related to U.S. Government resolutions (Note 16)	326		1,689	46,000
	70,846	69,853	217,768	262,158
Operating income	21,533	23,599	64,529	15,498
Other income and expense				
Interest expense, net	(465)	(2,267)	(3,950)	(6,880)
Other expense	(1,020)	(399)	(992)	(1,850)
	(1,485)	(2,666)	(4,942)	(8,730)
Income before income taxes	20,048	20,933	59,587	6,768
Income tax expense	(6,930)	(7,982)	(20,286)	(20,038)
Net income (loss) from continuing operations, net of tax	13,118	12,951	39,301	(13,270)
Discontinued operations (Note 15)				
Gain on sale of Breg, Inc., net of tax	221		1,261	
Income (loss) from discontinued operations	(9,046)	(553)	(15,398)	123
Income tax benefit (expense)	3,267	(20)	5,617	(318)
Net loss from discontinued operations, net of tax	(5,558)	(573)	(8,520)	(195)
Net income (loss)	\$ 7,560	\$ 12,378	\$ 30,781	\$ (13,465)
Net income (loss) per common share- basic:				
Net income (loss) from continuing operations, net of tax	\$ 0.69	\$ 0.70	\$ 2.08	\$ (0.73)
Net loss from discontinued operations, net of tax	(0.29)	(0.03)	(0.45)	(0.01)
Net income (loss) per common share- basic	\$ 0.40	\$ 0.67	\$ 1.63	\$ (0.74)
Net income (loss) per common share- diluted:				
Net income (loss) from continuing operations, net of tax	\$ 0.67	\$ 0.69	\$ 2.04	\$ (0.73)
Net loss from discontinued operations, net of tax	(0.28)	(0.03)	(0.45)	(0.01)

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

Net income (loss) per common share- diluted: \$ 0.39 \$ 0.66 \$ 1.59 \$ (0.74)

Weighted average number of common shares:

Basic 19,078,590 18,384,451 18,861,374 18,146,076

Diluted 19,533,021 18,850,625 19,300,263 18,146,076

Comprehensive income (loss) \$ 9,067 \$ 5,664 \$ 30,615 \$ (15,254)

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, 2012 and 2011**

(Unaudited, U.S. Dollars, in thousands)	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net income (loss)	\$ 30,781	\$ (13,465)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	15,465	17,276
Amortization of debt costs	1,556	938
Provision for doubtful accounts	9,099	7,057
Deferred income taxes	(3,362)	(2,305)
Share-based compensation	5,097	5,358
Provision for inventory obsolescence	1,966	3,465
Gain on sale of Breg, Inc.	(1,261)	
Excess tax benefit on non-qualified stock options	(2,321)	(1,575)
Other	(4,006)	1,304
Change in operating assets and liabilities, net of effect of disposition:		
Trade accounts receivable	(33,824)	(15,746)
Inventories	(959)	(14,510)
Escrow receivable	41,537	(586)
Prepaid expenses and other current assets	(2,337)	2,455
Trade accounts payable	2,100	(2,180)
Charges related to U.S. Government resolutions	1,689	46,000
Other current liabilities	7,175	6,110
Net cash provided by operating activities	68,395	39,596
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(18,212)	(16,826)
Capital expenditures for intangible assets	(422)	(495)
Payment made in connection with acquisition		(5,250)
Net proceeds from the sale of Breg, Inc.	153,773	
Net cash provided by (used in) investing activities	135,139	(22,571)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	24,406	18,890
Repayments of long-term debt	(188,695)	(3,750)
Payment of refinancing fees		(758)
Repayment of bank borrowings, net	(1,036)	(2,642)
Changes in restricted cash	(20,219)	(14,288)
Cash payment for purchase of minority interest in subsidiary		(517)
Excess tax benefit on non-qualified stock options	2,321	1,575
Net cash used in financing activities	(183,223)	(1,490)
Effect of exchange rate changes on cash	54	(76)
Net increase in cash and cash equivalents	20,365	15,459
Cash and cash equivalents at the beginning of the period	33,207	13,561

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

Cash and cash equivalents at the end of the period	\$ 53,572	\$ 29,020
--	-----------	-----------

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Notes to the Unaudited Condensed Consolidated Financial Statements

1. Summary of significant accounting policies

(a) Basis of presentation

The accompanying Unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S.) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures, normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S., have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. The balance sheet at December 31, 2011 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 Company s Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2011.

(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 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) Recently Issued Accounting Standards

On June 16, 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-05, *Presentation of Comprehensive Income*. This ASU eliminates the current option to present other comprehensive income and its components in the statement of changes in shareholders equity and increases the prominence of other comprehensive income in the statements by providing an alternative to present the components of net income and comprehensive income as either one continuous or two separate but consecutive financial statements. Companies are also required to present reclassification adjustments for items that are reclassified from other comprehensive income to net income within these statements. This standard is to be applied retrospectively and is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company adopted this ASU as of March 31, 2012 and it did not have a material impact on the Company s Consolidated financial statements.

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)****2. Inventories**

Inventories are valued at the lower of cost or estimated net realizable value, after provision for excess or obsolete items. Cost is determined on a weighted-average basis, which approximates the first in, first out (FIFO) method. The valuation of work-in-process, finished products, field inventory and consignment inventory includes the cost of materials, labor and production. Field inventory represents immediately saleable finished products inventory that is in the possession of the Company's direct sales representatives and independent distributors. Consignment inventory represents immediately saleable finished products located at third party customers, such as distributors and hospitals.

Inventories were as follows:

(US\$ in thousands)	September 30, 2012	December 31, 2011
Raw materials	\$ 9,210	\$ 10,115
Work-in-process	7,734	5,606
Finished products	45,718	49,141
Field inventory	38,041	39,400
Consignment inventory	7,085	7,551
	107,788	111,813
Less reserve for obsolescence	(26,966)	(28,844)
	\$ 80,822	\$ 82,969

3. Patents and other intangible assets

(US\$ in thousands)	September 30, 2012	December 31, 2011
Cost		
Patents and developed technologies	\$ 37,300	\$ 37,683
Trademarks - definite lived (subject to amortization)	624	545
	37,924	38,228
Accumulated amortization		
Patents and developed technologies	(30,514)	(29,611)
Trademarks - definite lived (subject to amortization)	(410)	(381)
Patents and other intangible assets, net	\$ 7,000	\$ 8,236

4. Goodwill

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

(US\$ in thousands)	Total
At December 31, 2011	\$ 73,094

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

Foreign currency	858
At September 30, 2012	\$ 73,952

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)****5. Bank borrowings**

Borrowings under lines of credit consist of borrowings in Euros used to fund international operations. The borrowings under such facilities were \$0.3 million and \$1.3 million at September 30, 2012 and December 31, 2011, respectively. The weighted average interest rates on borrowings under lines of credit as of September 30, 2012 and December 31, 2011 were 4.96% and 4.02%, respectively.

The Company had an unused available line of credit of 7.1 million (\$9.1 million) and 6.3million (\$8.1 million) at September 30, 2012 and December 31, 2011, respectively in its Italian line of credit. This line of credit is unsecured and provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

6. 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, \$200.0 million secured revolving credit facility (the Revolving Credit Facility), and a five year, \$100.0 million secured term loan facility (the Term Loan Facility), and together with the Revolving Credit Facility, the Credit Facilities). Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to \$50.0 million upon satisfaction of certain conditions.

In May 2012, the Company used a portion of the proceeds from the sale of Breg, Inc. (Breg) (see Note 15) to repay in full the remaining \$87.5 million balance on the Term Loan Facility and pay down \$57.5 million of amounts outstanding under the Revolving Credit Facility. This use of proceeds was required by the lenders' consent dated April 23, 2012 to the Credit Agreement. As a result of the sale of Breg, Breg ceased to be a subsidiary of the Company and, therefore, Breg was released as a credit party under the Credit Agreement. Additionally, the Company paid \$20 million in June and \$20 million in September 2012 to reduce amounts outstanding under the Revolving Credit Facility. As a result, at September 30, 2012, the Term Loan Facility had been repaid in full and there was \$20 million outstanding under the Revolving Credit Facility. As of December 31, 2011, the Company had \$91.3 million outstanding under the Term Loan Facility and \$117.4 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, 2012, the entire Revolving Credit Facility was at the LIBOR rate plus a margin of 2.50%. As of December 31, 2011, the entire Term Loan Facility and \$100 million of the Revolving Credit Facility was at the LIBOR rate plus a margin of 3.00%. As of December 31, 2011, the remaining \$17.4 million of the Revolving Credit Facility was at a base rate (as defined in the Credit Agreement) plus a margin of 2.00%. The effective interest rate on the Credit Facilities as of September 30, 2012 and December 31, 2011 was 2.74% and 3.4%, respectively.

Outstanding principal on the Revolving Credit Facility is 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. The Company was in compliance with the affirmative and negative covenants at September 30, 2012 and there were no events of default.

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)**

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, 2012 and December 31, 2011 was \$204.8 million and \$186.0 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Agreement, as amended, from access to cash held by Orthofix Holdings and its subsidiaries. The amount of cash restricted under this agreement as of September 30, 2012 and December 31, 2011 was \$67.3 million and \$45.5 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, 2012 and December 31, 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were \$2 million and \$3.5 million, respectively.

7. 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, 2012	Fair value: favorable (unfavorable)	Balance sheet location
Cross-currency swap	\$ 1,778	Other long-term assets
As of December 31, 2011		
Cross-currency swap	\$ 1,011	Other long-term assets

(US\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Cross-currency swap unrealized gain (loss) recorded in other comprehensive income (loss), net of taxes	\$ 253	\$ (927)	\$ 177	\$ 374

Cross-currency swap

In 2006, the Company entered into a cross-currency swap agreement with Wells Fargo 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. The derivative instrument, a ten-year fully amortizable agreement with an initial notional amount of \$63.0 million, was scheduled to expire on December 30, 2016. Upon executing the Company's Credit Agreement (See Note 6), the Company terminated this cross-currency swap agreement on September 30, 2010. Also on September 30, 2010, the Company entered into a new cross-currency swap agreement (the replacement swap) agreement with JPMorgan Chase Bank and Royal Bank of Scotland PLC (the counterparties). Upon the termination of the cross-currency swap agreement with Wells Fargo on September 30, 2010, the amount representing the current fair value of the terminated cross-currency swap was \$450,000 (the cash settlement amount). The cash settlement amount paid to Wells Fargo was recorded in other long-term assets on the condensed consolidated balance sheets and is being amortized over the remaining life of the underlying transaction, assuming such payments remain probable.

Under the terms of the replacement swap agreement, the Company pays Euros based on a \$33.5 million notional value and a fixed rate of 5.00% and receives U.S. dollars based on a notional value of \$45.5 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 replacement swap agreement applies, matures. The replacement 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).

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)****8. 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, 2012, 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 amount 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. The fair value of our Credit Facilities approximates book value as of September 30, 2012 because our interest rate was at the one month LIBOR plus an applicable margin.

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 estimated fair values. The Company has consistently applied these valuation techniques in all periods presented.

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

(US\$ in thousands)	Balance September 30, 2012	Level 1	Level 2	Level 3
Derivative financial instruments (1)				
Cash flow hedges				
Cross-currency hedge	\$ 1,778	\$	\$ 1,778	\$

(1) See Note 8, *Derivative Instruments*

(US\$ in thousands)	Balance December 31, 2011	Level 1	Level 2	Level 3
Derivative financial instruments(1)				
Cash flow hedges				

Cross currency hedge	\$	1,011	\$	\$ 1,011	\$
----------------------	----	-------	----	----------	----

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)****9. 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, 2011	\$ 1,893	\$ (132)	\$ 1,761
Unrealized gain on cross-currency swap, net of tax of \$102		177	177
Foreign currency translation adjustment (1)	(343)		(343)
Balance at September 30, 2012	\$ 1,550	\$ 45	\$ 1,595

- (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,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income (loss)	\$ 7,560	\$ 12,378	\$ 30,781	\$ (13,465)
Other comprehensive income (loss):				
Unrealized gain (loss) on cross-currency swap, net of tax	253	(927)	177	374
Foreign currency translation adjustment	1,254	(5,787)	(343)	(2,163)
Total comprehensive income (loss)	\$ 9,067	\$ 5,664	\$ 30,615	\$ (15,254)

10. Earnings per share

For the three and nine months ended September 30, 2012 and 2011, there were no adjustments to net income (loss) for purposes of calculating basic and diluted net income (loss) available to common shareholders. The following is a reconciliation of the weighted average shares used in the basic and diluted net income (loss) per common share computations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Weighted average common shares-basic	19,078,590	18,384,451	18,861,374	18,146,076
Effect of dilutive securities:				
Unexercised stock options net of treasury share repurchase	454,431	466,174	438,889	

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

Weighted average common shares-diluted	19,533,021	18,850,625	19,300,263	18,146,076
--	------------	------------	------------	------------

No adjustment has been made in the nine months ended September 30, 2011 for any common stock equivalents because their effects would be anti-dilutive on net loss for this period. For the nine months ended September 30, 2011, potentially dilutive shares totaled 331,775.

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 636,900 and 688,636 outstanding options not included 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. There were 787,440 and 2,600,874 outstanding options not included, respectively, in the diluted earnings per share computation for the three and nine months ended September 30, 2011, respectively, because the inclusion of these options was anti-dilutive.

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)****11. Share-based compensation**

All share-based compensation costs are measured at the grant date, based on the estimated fair value of the award, and are recognized as expense in the condensed consolidated statements of operations over the requisite service period.

The following table shows the detail of share-based compensation by line item in the condensed consolidated statements of operations:

(US\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Cost of sales	\$ 155	\$ 34	\$ 438	\$ 106
Sales and marketing	598	439	1,440	1,549
General and administrative	1,309	793	2,851	3,282
Research and development	34	31	105	129
Total	\$ 2,096	\$ 1,297	\$ 4,834	\$ 5,066

There were no performance requirements or market conditions for share-based compensation awarded to employees.

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. During the three and nine months ended September 30, 2011, there were 169,110 and 684,428 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

12. Income taxes

For Continuing Operations the Company recognized a \$20.3 million and \$20.0 million provision for income tax which reflects an effective tax rate of 34% on pre-tax income and (296.1%) on a pre-tax loss for the nine months ended September 30, 2012 and 2011, respectively. Excluding the impact of discrete charges related to the U.S. Government resolutions, the effective tax rate on continuing operations for the first nine months of 2012 and 2011 was 36.6% and 38.0%, respectively. The principal factors affecting the Company's effective tax rate for the first nine months of 2012 were the tax benefit of discrete items related to the U.S. Government resolutions, 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 effective tax rate for the first nine months of 2011 was impacted by discrete charges related to U.S. Government inquiries, for which no tax benefit was recorded, the mix of earnings among tax jurisdictions, state taxes and current period losses in certain foreign jurisdictions for which the Company does not currently provide a tax benefit.

As of September 30, 2012 and December 31, 2011, the Company's gross unrecognized tax benefit was \$0.6 million and \$0.7 million, respectively. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits in income tax expense. The Company had approximately \$0.5 million accrued for payment of interest and penalties as of September 30, 2012 and December 31, 2011. The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company's effective tax rate if recognized. As of September 30, 2012, the Company does not expect the amount of unrecognized tax benefits to change significantly over the next twelve months.

The Company files a consolidated income tax return in the U.S. federal jurisdiction and numerous consolidated and separate income tax returns in many state and foreign jurisdictions. The statute of limitations with respect to federal tax authorities is closed for years prior to December 31, 2009. The statute of limitations for the various state tax filings is closed in most instances for years prior to December 31, 2007. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to December 31, 2006.

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)****13. Business segment information**

The Company's segment information (as provided below) has been prepared based on the Company's two GBU reporting segments, Spine and Orthopedics. The accounting policies of the segments are the same as those described in the business segment information found in Note 12 to the Consolidated Financial Statements included in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2011.

The tables below present external net sales for continuing operations by GBU reporting segment:

(US\$ in thousands)	External Net Sales by GBU Three Months Ended September 30,			
	2012	2011	Reported Growth	Constant Currency Growth
Spine				
Spine Repair Implants and Regenerative Biologics	\$ 36,634	\$ 36,769	%	%
Spine Regenerative Stimulation	42,759	39,734	8%	8%
Total Spine	79,393	76,503	4%	4%
Orthopedics				
	35,359	40,803	(13)%	(4)%
Total Net Sales	\$ 114,752	\$ 117,306	(2)%	1%

(US\$ in thousands)	External Net Sales by GBU Nine Months Ended September 30,			
	2012	2011	Reported Growth	Constant Currency Growth
Spine				
Spine Repair Implants and Regenerative Biologics	\$ 110,892	\$ 107,608	3%	3%
Spine Regenerative Stimulation	125,325	118,012	6%	6%
Total Spine	236,217	225,620	5%	5%
Orthopedics				
	114,069	121,416	(6)%	1%
Total Net Sales	\$ 350,286	\$ 347,036	1%	3%

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)**

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

Operating Income (Loss) by GBU (US\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Spine (1)	\$ 22,615	\$ 22,373	\$ 65,209	\$ 28,239
Orthopedics (2)	3,274	4,501	12,347	5,842
Corporate (3)	(4,356)	(3,275)	(13,027)	(18,583)
Total	\$ 21,533	\$ 23,599	\$ 64,529	\$ 15,498

- (1) For the nine months ended September 30, 2012 and 2011, the operating income for the Spine GBU included \$1.5 million and \$36.5 million, respectively, of expenses in connection with charges related to U.S. Government resolutions. For the nine months ended September 30, 2012, the operating income for the Spine GBU included a \$3.1 million charge for an arbitration resolution related to a 2008 co-development agreement and a \$2.3 million charge for costs related the Company's strategic investment with MTF.
- (2) For the nine months ended September 30, 2012 and 2011, the operating income for the Orthopedics GBU included \$0.2 million and \$6.5 million, respectively, of expenses in connection with charges related to U.S. Government resolutions. For the nine and three months ended September 30, 2012, the operating income for the Orthopedics GBU included a \$0.7 million and \$0.5 million charge, respectively, of costs related the Company's strategic investment with MTF.
- (3) For the nine months ended September 30, 2011, the operating loss for the Corporate GBU included \$3 million of expenses in connection with charges related to U.S. Government resolutions and \$3.2 million of senior management succession charges.

14. Sale of Breg and Disposition of Sports Medicine GBU

On April 23, 2012, the Company's subsidiary Orthofix Holdings and Breg entered into a stock purchase agreement (the "SPA") with Breg Acquisition Corp. ("Buyer"), a newly formed affiliate of Water Street Healthcare Partners II, L.P., pursuant to which Buyer agreed to acquire from Orthofix Holdings all the outstanding shares of Breg, subject to the terms and conditions contained therein (the "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, and 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 16.") On May 24, 2012 (the "Closing Date"), Orthofix Holdings completed the sale of all of the outstanding shares of Breg for \$157.5 million in cash. After adjustments for working capital and indebtedness in accordance with the terms of the SPA, Orthofix Holdings used \$145 million of the net proceeds to prepay outstanding Company indebtedness, as required by a lender consent received in connection with the Company's existing Credit Agreement. As a result of the closing of this Transaction, Breg ceased to be a subsidiary of the Company and, therefore, Breg was released as a credit party under the Credit Agreement. The Company also agreed to enter into certain transition arrangements at the closing, including a transition services agreement pursuant to which the Company agreed to continue to provide administrative operational support for a period of up to twelve months. As a result of the sale of Breg, the Company completed its exit from the Sports Medicine GBU, of which Breg was a significant component.

The portion of indemnification related to post closing claims related to post-closing sales of cold therapy has created a guarantee under Accounting Standards Codification ASC 460 "Guarantees" and the fair value of the liability has been recorded under the initial recognition criteria in the amount of \$2 million at the Closing Date of the transaction. 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 \$1.8 million as of September 30, 2012.

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)****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 six months ended September 30, 2012.

(US\$ in thousands)	Total
Cash proceeds	\$ 157,500
Less:	
Working Capital	(7,093)
Transaction related expenses	(4,258)
Fair Value of Indemnification	(2,000)
Tangible assets	(8,309)
Intangible assets	(28,164)
Goodwill	(106,200)
Gain on sale of Breg	1,476
Income tax expense	(215)
Gain on sale of Breg, net of taxes	\$ 1,261

The Sports Medicine GBU contributed \$43.6 million and \$80.4 million of net sales in the nine months ended September 30, 2012 and 2011, respectively. The Sports Medicine GBU contributed \$0.2 million and \$27.4 million of net sales in the three months ended September 30, 2012 and 2011, respectively. The Sports Medicine GBU had \$14.3 million of operating losses and less than \$0.1 million of operating income in the nine months ended September 30, 2012 and 2011, respectively. The Sports Medicine GBU had \$9.3 million and \$0.6 million of operating losses in the three months ended September 30, 2012 and 2011, respectively. The financial information above includes the financial results of Breg operations up to the date of sale.

The Company's consolidated financial statements and related footnote disclosures reflect the Sports Medicine GBU as discontinued operations. Income (loss) associated with the Sports Medicine GBU, net of applicable income taxes is shown as income (loss) from discontinued operations for all periods presented in accordance with *ASC 205-20 Discontinued Operations*. In addition, the assets and liabilities of the discontinued entity have been reclassified and presented as assets held for sale and liabilities held for sale in the Company's balance sheet as of December 31, 2011.

The assets and liabilities of the discontinued operations are as follows:

(US\$ in thousands)	December 31, 2011
Assets Held for Sale	
Restricted cash	\$ 1,629
Trade accounts receivable, less allowance	13,711
Inventories, net	8,277
Property, plant and equipment, net	8,756
Intangible assets, net	29,279
Goodwill	106,279
Deferred income taxes, prepaid expenses and other assets	3,254
Assets Held for Sale	\$ 171,185

Liabilities Held for Sale

Trade accounts payable	3,616
Deferred income taxes and other liabilities	19,060

Liabilities Held for Sale	\$ 22,676
----------------------------------	------------------

Table of Contents

Notes to the Unaudited Condensed Consolidated Financial Statements (continued)

15. Contingencies

The Company is a party to certain outstanding legal proceedings, investigations and claims. These matters are described in the Company's Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2011, as well as the Company's Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2012 and June 30, 2012. Material recent developments regarding such matters are described below.

The Company believes that it is unlikely that the outcome of any or all of these matters will have a material adverse effect on the Company and its subsidiaries as a whole, notwithstanding that the unfavorable resolution of any matter may have a material effect on the Company's net earnings (if any) in any particular quarter. However, the Company cannot predict with any certainty the final outcome of any outstanding legal proceedings, investigations or claims made against it or its subsidiaries described in the above-referenced documents and below, and there can be no assurance that the ultimate resolution of any such matter will not have a material adverse impact on the Company's consolidated financial position, results of operations, or cash flows.

The Company records accruals for certain of its outstanding legal proceedings, investigations or claims when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, the Company does not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then the Company discloses a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If the Company cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed.

The assessments of whether a loss is probable or a reasonable possibility, and whether the loss or range of loss is reasonably estimable, often involve a series of complex judgments about future events. Among the factors that the Company considers in this assessment are the nature of existing legal proceedings, investigations and claims, the asserted or possible damages or loss contingency (if reasonably estimable), the progress of the matter, existing law and precedent, the opinions or views of legal counsel and other advisers, the involvement of the U.S. Government and its agencies in such proceedings, the Company's experience in similar matters and the experience of other companies, the facts available to the Company at the time of assessment, and how the Company intends to respond, or has responded, to the proceeding, investigation or claim. The Company's assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where the Company is not currently able to reasonably estimate a range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the matters are in the early stages, (iii) the matters involve novel or unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement have not reached the point where the Company believes a reasonable estimate of loss, or range of loss, can be made. In such instances, the Company believes that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

In addition to the matters specifically identified in the paragraphs below, in the normal course of our business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies. To the extent losses related to these contingencies are both probable and reasonably estimable, the Company accrues appropriate amounts in the accompanying financial statements and provides disclosures as to the possible range of loss in excess of the amount accrued, if such range is reasonably estimable. The Company believes losses are individually and collectively immaterial as to a possible loss and range of loss.

Litigation Matter Updates:

Matters Related To Blackstone Medical, Inc.

As previously disclosed, in January 2012, after a series of ongoing discussions and negotiations with the U.S. Attorney's Office for the District of Massachusetts (the Boston USAO), the Company's board of directors approved an agreement in principle to pay \$32 million to resolve a government investigation and related qui tam complaint related to the compensation of physician consultants by the Company's subsidiary, Blackstone Medical, Inc. (Blackstone). This investigation was focused mainly on conduct that occurred prior to the Company's acquisition of Blackstone in 2006. As such, the Company received a payment from the escrow fund established in connection with the Company's acquisition of Blackstone in 2006 that funds this settlement.

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

The Company recorded charges of \$0.3 million and \$0.1 million in the nine months ended and the three months ended September 30, 2012, respectively, which represent imputed interest on the settlement accrued as of September 30, 2012. On October 29, 2012, Blackstone entered into a written settlement agreement with the U.S. government and the qui tam relator, which agreement settles this matter on the terms described above. On October 30, 2012 the Company made these settlement payments.

Table of Contents

Matters Related to Regenerative Stimulation Business

As previously disclosed, in June 2012, the Company entered into a definitive settlement agreement with the United States of America, acting through DOJ and on behalf of HHS-OIG, the TRICARE Management Activity, through its General Counsel, the Office of Personnel Management, in its capacity as administrator of the Federal Employees Health Benefits Program, the United States Department of Veteran Affairs and a qui tam relator. The agreement settled a government investigation and related qui tam complaint related to our Regenerative stimulation business. In connection with the settlement agreement, the Company's wholly-owned subsidiary, Orthofix Inc., entered into a plea agreement with the Boston USAO and DOJ under which Orthofix Inc. agreed to plead guilty to one felony count of obstruction of a June 2008 federal audit (§18 U.S.C. 1516). This plea agreement currently remains subject to review and approval by the U.S. District Court for the District of Massachusetts, and there can be no assurance that the plea agreement will be approved by the court on the terms proposed.

The Company has agreed to pay \$34.2 million (plus interest at a rate of 3% from May 5, 2011 through the day before payment is made) under the terms of the settlement agreement. Under the plea agreement, Orthofix Inc. has agreed to pay (i) a criminal fine of \$7.8 million, and (ii) a mandatory special assessment of \$400. In addition, the Company agreed in July 2012 to pay Mr. Bierman's counsel \$1.0 million in fees. The Company previously recorded a charge of \$43 million during the first quarter of 2011 in anticipation of the settlement. The Company recorded charges of \$1.4 million and \$0.3 million in the nine months ended and the three months ended September 30, 2012, respectively, which represent imputed interest on the settlement accrued as of September 30, 2012.

Corporate Integrity Agreement with HHS-OIG

As previously disclosed, in June 2012, in connection with the Company's settlement of the matters described above related to the Company's Regenerative stimulation business, and in anticipation of the final settlement of the government investigation and related qui tam complaint described above related to Blackstone, the Company also entered into a five-year corporate integrity agreement with HHS-OIG (the "CIA"). The Company is currently in the process of undertaking its obligations under the CIA.

Matters Related to Promeca

On July 10, 2012, the Company entered into definitive agreements memorializing the previously disclosed agreement in principle previously reached with DOJ and the Securities and Exchange Commission (the "SEC") regarding the Company's self-initiated and self-reported internal investigation of its Mexican subsidiary, Promeca S.A. de C.V. ("Promeca"), into allegations of non-compliance by Promeca with the Foreign Corrupt Practices Act ("FCPA"). As part of the settlement of this matter, the Company entered into (i) a consent to final judgment (the "SEC Consent") with the SEC and (ii) a deferred prosecution agreement (the "DPA") with the DOJ. The U.S. District Court for the Eastern District of Texas, Sherman Division, which has jurisdiction over the matter, entered final judgment on September 4, 2012 in accordance with the terms of the SEC Consent.

Under the terms of the SEC Consent, the Company settled civil claims related to this matter by voluntarily disgorging profits to the United States government in an amount of \$5.2 million, inclusive of pre-judgment interest. The Company also agreed to pay a fine of \$2.2 million to the United States government pursuant to the terms of the DPA. The Company previously recorded charges of \$3.0 million during the first quarter of 2011 and \$4.5 million during the fourth quarter of 2011 to establish an accrual in anticipation of a future final resolution of these matters with both the DOJ and the SEC. The Company made each of these settlement payments in the third quarter of 2012. The Company is currently in the process of undertaking its obligations under the DPA.

Matters Related to the Company's Former Breg Subsidiary and Possible Indemnification Obligations

On May 24, 2012, the Company sold Breg to an affiliate of Water Street Healthcare Partners II, L.P. ("Water Street") pursuant to a stock purchase agreement (the "Breg SPA"). Under the terms of the Breg SPA, upon closing of the sale, the Company and its subsidiary, Orthofix Holdings, Inc., agreed to indemnify Water Street and Breg with respect to certain specified matters, including (i) the government investigation and product liability matters regarding the previously owned infusion pump product line described above, and (ii) pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units, including the product liability cases with respect to such products described above. The Company has established an accrual of \$2.0 million, and had recorded the related charge to discontinued operations, for its indemnification obligations in connection with certain post-closing sales of cold therapy units. This accrual was approximately \$1.8 million as of September 30, 2012. The Company has not established any accrual in connection with its other indemnification obligations under the Breg SPA, and currently cannot reasonably estimate the possible loss, or range of loss, in connection with such obligations.

In July 2012, a jury in one case related to a motorized cold therapy unit previously sold by Breg returned a verdict providing for approximately \$2.1 million in compensatory damages to the plaintiff against Breg and \$7 million in exemplary damages. The case remains subject to further

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

post-verdict motions and appeals. The Company believes that the exemplary damages are without merit, however, the ultimate outcome is uncertain. The Company has established an accrual and related charge to discontinued operations of \$4.2 million for both compensatory damages and exemplary damages for its indemnification obligations in connection with this July 2012 verdict; however, actual liability in this case could be higher or lower than the amount accrued.

Table of Contents

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

The following discussion and analysis addresses our liquidity, financial condition and results of operations for the three and nine months ended September 30, 2012 compared to our results of operations for the three and nine months ended September 30, 2011. 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 Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K, as amended for the fiscal year ended December 31, 2011.

General Overview

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

We have administrative and training facilities in the United States (U.S.) and Italy and manufacturing facilities in the U.S., the United Kingdom, and Italy. We directly distribute our products in the U.S., the United Kingdom, Italy, Germany, Switzerland, Austria, France, Belgium, Brazil and Puerto Rico. In several markets, we distribute our products through independent distributors.

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

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

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

Our segment information is prepared on the same basis that management reviews the financial information for operational decision making purposes. At this time, our Chief Operating Decision Maker (the CODM) only uses global business units (GBUs) reporting for Sales and Operating Income to assess operating performance. Items below operating income are not considered when measuring the profitability of a segment. In the future, the CODM may decide to review other financial metrics by GBU. Goodwill is also assigned to specific GBUs. We neither discretely allocate assets, other than goodwill, to our operating segments nor evaluate the operating segments using discrete asset information. We manage our business by our two GBUs, which are comprised of Spine and Orthopedics supported by Corporate activities. These GBUs represent the segments for which our CODM reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information has been prepared based on our two GBUs reporting segments. These two segments are discussed below.

Spine

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

Table of Contents*Orthopedics*

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

Corporate

Corporate activities are comprised of the operating expenses of Orthofix International N.V. and its U.S. holding company subsidiary, Orthofix Holdings, Inc., along with activities not necessarily identifiable with the two GBUs.

GBU Revenues

The following tables display net sales by GBU for the three and nine months ended September 30, 2012 and 2011. We assess our performance based on these GBUs. We maintain our records and account for net sales, costs of sales and expenses by GBU.

The tables below present external net sales from continuing operations by GBU:

(US\$ in thousands)	External Net Sales by GBU Three Months Ended September 30,			
	2012	2011	Reported Growth	Constant Currency Growth
Spine				
Spine Repair Implants and Regenerative Biologics	\$ 36,634	\$ 36,769	%	%
Spine Regenerative Stimulation	42,759	39,734	8%	8%
Total Spine	79,393	76,503	4%	4%
Orthopedics	35,359	40,803	(13)%	(4)%
Total Net Sales	\$ 114,752	\$ 117,306	(2)%	1%

(US\$ in thousands)	External Net Sales by GBU Nine Months Ended September 30,			
	2012	2011	Reported Growth	Constant Currency Growth
Spine				
Spine Repair Implants and Regenerative Biologics	\$ 110,892	\$ 107,608	3%	3%
Spine Regenerative Stimulation	125,325	118,012	6%	6%
Total Spine	236,217	225,620	5%	5%
Orthopedics	114,069	121,416	(6)%	1%
Total Net Sales	\$ 350,286	\$ 347,036	1%	3%

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012 (%)	2011 (%)	2012 (%)	2011 (%)
Net sales	100	100	100	100
Cost of sales	19	20	19	20
Gross profit	81	80	81	80
Operating expenses:				
Sales and marketing	43	42	42	42
General and administrative	12	12	13	14
Research and development	6	5	7	5
Amortization of intangible assets	0	1	0	0
Charges related to U.S. Government inquiries	0	0	1	13
Operating income	19	20	18	5
Net income (loss)	7	11	9	(4)

Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011

Net sales decreased \$2.5 million to \$114.8 million in the third quarter of 2012 compared to \$117.3 million for the same period last year. The impact of foreign currency decreased sales by \$3.8 million during the third quarter of 2012 when compared to the third quarter of 2011.

Sales

Net sales in our Spine global business unit increased to \$79.4 million in the third quarter of 2012 compared to \$76.5 million for the same period last year, an increase of \$2.9 million. The increase in Spine's net sales was primarily the result of a 8% increase in the sales of our Regenerative Stimulation products used in Spine applications when compared to the prior year. Revenue from our Repair Implants and Regenerative Biologics revenue products in the third quarter of 2012 was flat when compared to the same period in the prior year. The year over year comparison includes the increased adoption of Trinity Evolution® in spine applications which led to a 21% increase in sales of Regenerative Biologics in the third quarter of 2012 which was primarily offset by the decrease in sales of Repair Implants in our international markets.

Net sales in our Orthopedics global business unit decreased 13% (but decreased 4% on a constant currency basis) to \$35.4 million in the third quarter of 2012 compared to \$40.8 million for the same period last year. This constant currency decrease was driven mostly by weaker Physio-Stim sales and challenges in Brazil, which has been impacted by increased competition and product delays due to the strike at the country's regulatory agency partially offset by an 18% increase in Regenerative Biologics in Orthopedics applications.

Gross Profit Our gross profit decreased \$1.1 million to \$92.4 million in the third quarter of 2012 compared to \$93.5 million for the same period last year. Gross profit as a percent of net sales in the third quarter of 2012 was 80.5% for the third quarter of 2012 and 79.7% for 2011 during the same period.

Sales and Marketing Expense Sales and marketing expense, which includes commissions, certain royalties and bad debt provision, generally increase or decrease in relation to sales. Sales and marketing expense decreased \$0.1 million, to \$49.3 million in the third quarter of 2012 compared to \$49.4 million in the third quarter of 2011. As a percent of net sales, sales and marketing expense was 43% and 42.1% in the third quarter of 2012 and 2011, respectively. This increase percentage was driven by an increase in bad debt expense.

General and Administrative Expense General and administrative expense decreased \$0.2 million, in the third quarter of 2012 to \$13.8 million compared to \$14 million in the third quarter of 2011. Stock-based compensation expense increased by \$0.5 million in the third quarter of 2012 versus 2011. We incurred \$0.5 million and \$1 million of expenses in the third quarter of 2012 and 2011, respectively, related to regenerative stimulation and Mexico FCPA investigations. General and administrative expense as a percent of net sales was 12.1% in the third quarter of 2012 compared to 11.9% for the same period last year.

Research and Development Expense Research and development expense increased \$0.9 million in the third quarter of 2012 to \$6.9 million compared to \$6 million in the third quarter of 2011. The increase in research and development expenses in the third quarter of 2012 compared to

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

the same period in the prior year was due to a \$2 million strategic investment with MTF. As a percent of sales, research and development expense was 6% in the third quarter of 2012 compared to 5.1% for the same period last year.

Table of Contents

Amortization of Intangible Assets Amortization of intangible assets remained flat at \$0.5 million in the third quarter of 2012 and 2011.

Charges Related to U.S. Government Resolutions We recorded a charge of \$0.4 million in the third quarter of 2012 which represents imputed interest accrued on the previously disclosed settlements in principle of the U.S. government investigations and related qui tam complaints related to our regenerative stimulation business and Blackstone Medical Inc.

Interest Expense, net Interest expense, net was \$0.5 million for the third quarter of 2012 compared to \$2.3 million for the same period last year, primarily as the result of a lower year over year outstanding debt balance and to a lesser extent, lower interest rates.

Other Income and Expense Other expense was \$1 million and \$0.4 million for the third quarters of 2012 and 2011, respectively. The fluctuation is in part 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 on continuing operations was 34.6% and 38.1% during the third quarters of 2012 and 2011, respectively. The effective tax rate for the third quarter of 2012 and 2011 was affected by our mix of earnings among various tax jurisdictions, state taxes and current period losses in certain jurisdictions for which we do not currently provide a tax benefit. The third quarter of 2012 rate was also affected by the tax benefit of discrete items related to the U.S. Government resolutions. Excluding the impact of discrete charges the effective tax rate for the third quarter of 2012 was 35.9%.

Discontinued operations Discontinued operations in the third quarter of 2012 include \$5.8 million of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to its former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters. Discontinued operations in the third quarter of 2011 includes the results of our Sports Medicine GBU, net of income taxes.

Net Income Net income for the third quarter of 2012 was \$7.6 million, or \$0.40 per basic and \$0.39 per diluted share, compared to net income of \$12.4 million, or \$0.67 per basic share and \$0.66 per diluted share for the same period last year.

Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011

Net sales increased \$3.3 million to \$350.3 million in the first nine months of 2012 compared to \$347 million for the same period last year. The impact of foreign currency decreased sales by 8.3 million during the first nine months of 2012 when compared to the same period of 2011.

Sales

Net sales in our Spine global business unit increased to \$236.2 million in the first nine months of 2012 compared to \$225.6 million for the same period last year, an increase of \$10.6 million. The increase in Spine's net sales was primarily the result of a 3% increase in sales of our Repair and Regenerative Biologics revenue products in the first nine months of 2012 when compared to the same period in the prior year due to increased adoption of Trinity Evolution® in spine applications which led to a 38% increase in sales of Regenerative Biologics in the first nine months of 2012. The Regenerative Stimulations products used in Spine applications increased 6% when compared to the prior year.

Net sales in our Orthopedics global business unit decreased 6% (but increased 1% on a constant currency basis) to \$114.1 million in the first nine months of 2012 compared to \$121.4 million for the same period last year. The constant currency sales growth was led by sales of Trinity Evolution® in Orthopedic applications which resulted in an 13% increase in Regenerative Biologics. Also contributing to the growth was the recently launched internal fixation systems for the foot and ankle.

Gross Profit Our gross profit increased \$4.6 million to \$282.3 million in the first nine months of 2012, compared to \$277.7 million for the same period last year. Gross profit as a percent of net sales in the first nine months of 2012 was 80.6% for the first nine months of 2012 and 80% in 2011 during the same period.

Sales and Marketing Expense Sales and marketing expense, which includes commissions, certain royalties and bad debt provision, generally increase or decrease in relation to sales. Sales and marketing expense increased \$1.8 million, to \$148.6 million in the first nine months of 2012 compared to \$146.8 million in the first nine months of 2011. As a percent of net sales, sales and marketing expense was 42.4% and 42.3% in the first nine months of 2012 and 2011, respectively.

Table of Contents

General and Administrative Expense General and administrative expense decreased \$7.4 million, or 14.8%, in the first nine months of 2012 to \$42.7 million compared to \$50.1 million in the first nine months of 2011. General and administrative expense as a percent of net sales was 12.2% in the first nine months of 2012 compared to 14.4% for the same period last year. The decrease in general and administrative expense relates to decreased legal costs associated with various legal matters. We incurred \$1.7 million and \$7.6 million of expenses in the first nine months of 2012 and 2011, respectively, related to regenerative stimulation and Mexico FCPA investigations. During the first nine months of 2011, we also incurred \$3.2 million of senior management succession charges.

Research and Development Expense Research and development expense increased \$5.5 million in the first nine months of 2012 to \$23.2 million compared to \$17.7 million for the same period last year. As a percent of sales, research and development expense was 6.6% in the first nine months of 2012 compared to 5.1% for the same period last year. The increase in research and development expenses in the first nine months of 2012 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, a \$3 million strategic investment with Musculoskeletal Transplant Foundation (MTF) on the development and commercialization of the next generation cell-based bone growth technology and timing of spending related to our ongoing research, development and clinical activities.

Amortization of Intangible Assets Amortization of intangible assets was \$1.6 million in the first nine months of 2012 and 2011.

Charges Related to U.S. Government Resolutions We recorded a charge of \$1.7 million in the first nine months of 2012 which represents imputed interest accrued from the respective settlement in principle dates in 2011 and 2012 through September 30, 2012 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., respectively. During the first nine months of 2011, we reached an agreement in principle with the U.S. Government to resolve criminal and civil matters related to the previously disclosed government investigations of our regenerative stimulation business and recorded a charge of \$43 million for the estimated settlement. During the first nine months of 2011, we recorded a charge of \$3 million to establish an accrual in connection with the fines and penalties related to the FCPA matter involving our former distribution entity.

Interest Expense, net Interest expense, net was \$4 million for the first nine months of 2012 compared to \$6.9 million for the same period last year, primarily as the result of a lower year over year outstanding debt balance and to a lesser extent, lower interest rates.

Other Income and Expense Other expense was \$1 million and \$1.9 million for the first nine months of 2012 and 2011, 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 on continuing operations was 34% and (296.1%) during the first nine months of 2012 and 2011, respectively. The principal factors affecting our effective tax rate for the first nine months of 2012 were the tax benefit of discrete items related to the U.S. Government resolutions, our mix of earnings among various tax jurisdictions, state taxes and current period losses in certain jurisdictions for which we do not currently provide a tax benefit. We do not believe that it is more likely than not that we will generate sufficient future income in these jurisdictions to allow for the utilization of these losses before their expiration. The effective tax rate for the first nine months of 2011 was impacted by discrete charges related to U.S. Government resolutions, for which we recorded no tax benefit, the mix of earnings among tax jurisdictions, state taxes and current period losses in certain foreign jurisdictions for which we do not currently provide a tax benefit. In the first nine months of 2011, we did not record a tax benefit associated with the expense attributable to the charges related to U.S. Government resolutions due to the uncertainty of the extent to which these expenses would be deductible for income tax purposes at that time. Excluding the impact of the discrete charges the effective tax rate for the first nine months of 2012 and 2011 was 36.6% and 38%, respectively.

Discontinued operations Discontinued operations in the first nine months of 2012 include \$8.6 million of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to its former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters. The first nine months of 2012 also include the gain on the sale of Breg, of \$1.3 million and the results of our Sports Medicine GBU up to May 24, 2012 (the closing date of the sale of Breg), net of income taxes. Discontinued operations in the first nine months of 2011 include the results of our Sports Medicine GBU, net of income taxes.

Net Income Net income for the first nine months of 2012 was \$30.8 million, or \$1.63 per basic and \$1.59 per diluted share, compared to net loss of \$13.5 million, or \$(0.74) per basic share and diluted share for the same period last year.

Table of Contents**Liquidity and Capital Resources**

Cash and cash equivalents including Restricted Cash at September 30, 2012 were \$120.9 million, of which \$67.3 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$78.7 million at December 31, 2011, of which \$45.5 million was subject to certain restrictions under the senior secured credit agreement discussed below.

Net cash provided by operating activities was \$68.4 million and \$39.6 million for the nine months ended September 30, 2012 and 2011, respectively. Net cash provided by operating activities is comprised of net income (loss), non-cash items (including depreciation and amortization, provision for doubtful accounts, provision for inventory obsolescence, share-based compensation, deferred income taxes, gain on sale of Breg, Inc.) and changes in working capital. Net income increased \$44.3 million to net income of \$30.8 million for the nine months ended September 30, 2012 from a net loss of \$13.5 million for the comparable period in the prior year. Non-cash items for the nine months ended September 30, 2012 decreased \$7.4 million to \$6.8 million compared to non-cash items of \$14.2 million in the same period of 2011. Working capital accounts consumed \$27.9 million and \$23.9 million of cash for the nine months ended September 30, 2012 and 2011, respectively. 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. A \$32 million portion of this amount was earmarked for payment of the Blackstone settlement which occurred on October 30, 2012.

For the nine months ended September 30, 2011, working capital accounts were impacted by charges related to U.S. Government resolutions of \$46 million, which offset the net loss recorded during the same period for those matters. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory reflect days sales in receivables of 125 days at September 30, 2012 and 102 days at September 30, 2011 excluding our former sports medicine global business unit, and inventory turns of 1.1 times as of September 30, 2012 and 2011. The increase in DSO during the period was partially related to the additional working capital investment made associated with our MTF partnership.

Net cash provided by investing activities was \$135.1 million for the nine months ended September 30, 2012 compared to net cash used in investing activities of \$22.6 million for the nine months ended September 30, 2011. During the second quarter of 2012 we sold Breg, Inc. for net proceeds of \$153.8 million. During the second quarter of 2011, we acquired 100% of the stock of Omni Motion, Inc. for a cash purchase price of \$5.3 million plus acquisition costs. During the nine months ended September 30, 2012 and 2011, we invested \$18.6 million and \$17.3 million in capital expenditures, respectively.

Net cash used in financing activities was \$183.2 million for the nine months ended September 30, 2012 compared to \$1.5 million for the nine months ended September 30, 2011. During the nine months ended September 30, 2012, we repaid approximately \$188.7 million against the principal on our senior secured term loan and revolving debt with a portion of the proceeds from the sale of Breg, Inc. and available cash compared to \$3.8 million during the nine months ended September 30, 2011. Our restricted cash balance usage increased \$5.9 million to \$20.2 million primarily related to the cash received from the Blackstone escrow fund which is recorded in Restricted Cash in accordance with the credit facility. During the nine months ended September 30, 2012 and 2011, we received proceeds of \$24.4 million and \$18.9 million, respectively, from the issuance of 814,022 shares and 684,428 shares, respectively, of our common stock related to stock purchase plan issuances, stock option exercises, and the vesting of restricted stock awards.

On August 30, 2010, our wholly-owned U.S. holding company, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a Credit Agreement (the Credit Agreement) with certain of our domestic direct and indirect subsidiaries (the Guarantors), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto.

The Credit Agreement provides for a five year, \$200.0 million secured revolving credit facility (the Revolving Credit Facility), and a five year, \$100.0 million secured term loan facility (the Term Loan Facility), and together with the Revolving Credit Facility, the Credit Facilities). Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to \$50 million upon satisfaction of certain conditions.

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

Table of Contents

As of September 30, 2012, the Term Loan Facility had been repaid in full and there was \$20 million outstanding under the Revolving Credit Facility. As of December 31, 2011, we had \$91.3 million outstanding under the Term Loan Facility and \$117.4 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, 2012, the entire Revolving Credit Facility was at the LIBOR rate plus a margin of 2.50%. As of December 31, 2011, the entire Term Loan Facility and \$100 million of the Revolving Credit Facility was at the LIBOR rate plus a margin of 3.00%. As of December 31, 2011, the remaining \$17.4 million of the Revolving Credit Facility was at a base rate (as defined in the Credit Agreement) plus a margin of 2.00%. The effective interest rate on the Credit Facilities at September 30, 2012 was 2.74% and at December 31, 2011 was 3.4%.

Outstanding principal on the Revolving Credit Facility is 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.

In May 2011, we obtained an amendment to the Credit Agreement to provide additional capacity under the various restrictive negative covenants for our payment of the Specified Settlement Amounts (as defined in the Credit Agreement, as amended) associated with each of the potential settlements (See Note 15 to the Unaudited Condensed Consolidated Financial Statements). The amendment updates the definition of Consolidated EBITDA to exclude Specified Settlement Amounts of up to \$50 million in the aggregate.

The Credit Agreement as amended requires us and Orthofix Holdings to comply with coverage ratios on a consolidated basis. The Credit Agreement contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. We believe we were in compliance with the affirmative and negative covenants at September 30, 2012. The Credit Agreement also includes events of default customary for facilities of this type. A breach of any of these covenants could result in an event of default under the Credit Agreement as amended, which could permit acceleration of the debt payments under the facility.

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, 2012 and December 31, 2011 was \$204.8 million and \$186 million, respectively. In addition, the Credit Agreement restricts us and our subsidiaries that are not parties to the Credit Agreement, as amended, from access to cash held by Orthofix Holdings and its subsidiaries. The amount of restricted cash as of September 30, 2012 and December 31, 2011 was \$67.3 million and \$45.5 million, respectively.

In conjunction with obtaining the Credit Facilities and the Credit Agreement, as amended, we 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, we wrote off \$0.8 million of related debt issuance costs. As of September 30, 2012 and December 31, 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were \$2 million and \$3.5 million, respectively.

At September 30, 2012, we had outstanding borrowings of 0.2 million (\$0.3 million) and unused available line of credit of approximately 7.1 million (\$9.1 million) under the line of credit established in Italy to finance the working capital of our Italian operations. The terms of the lines of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

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 lines of credit and our debt capacity are sufficient to cover the Specified Settlement Amounts, anticipated working capital and capital expenditure needs including research and development costs over the next twelve months.

Table of Contents

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 and the 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, 2012, we had a currency swap in place to minimize foreign currency exchange risk related to a 33.5 million intercompany note.

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, 2012, \$20 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00%. These margins are adjusted based upon the measurement of consolidated leverage ratio of our Company and our subsidiaries with respect to the immediately preceding four fiscal quarters. As of September 30, 2012, our effective interest rate on our Credit Facilities was 2.74%. Based on the balance outstanding under the Credit Facilities as of September 30, 2012, 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 \$0.4 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 goods currency exposure when we produce products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. As of September 30, 2012, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million (\$29.8 million). We recorded an unrealized foreign currency loss during the nine months ended September 30, 2012 of \$0.2 million related to this un-hedged long-term intercompany note, which resulted from the strengthening of the U.S. dollar against the Euro during the period. As this note is not expected to be repaid, we have considered such amounts to be permanently invested and therefore recorded such amount in accumulated other comprehensive income. For the nine months ended September 30, 2012, we recorded a foreign currency loss of \$0.1million on our condensed consolidated statements 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

Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Senior Vice President of Finance and Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) or 15d-15(e)) as of the end of the period covered by this Form 10-Q. Based upon that evaluation, our President and Chief Executive Officer and Senior Vice President of Finance and Chief Financial Officer concluded that, as of the end of the period covered by this Form 10-Q, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2012 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

See Note 15 *Contingencies* to our unaudited condensed consolidated financial statements contained in Item 1, *Financial Statements*, of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

Item 1 A. Risk Factors

The following risk factors supplement the risk factors contained in Part I, Item 1 A. Risk Factors, of our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2011, and should be read in conjunction with such risk factors:

Item 6. Exhibits

- 10.1 Amendment No. 1 to Amended and Restated Employment Agreement, dated as of August 29, 2012, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's current report on Form 8-K filed August 31, 2012 and incorporated herein by reference).
- 10.2 Amendment No. 3 to Amended and Restated Employment Agreement, dated as of August 29, 2012, by and between Orthofix Inc. and Michael Finegan (filed as an exhibit to the Company's current report on Form 8-K filed August 31, 2012 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, 2012 formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows and (iv) related notes, detail tagged.

* Filed herewith.

+ Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. This exhibit has been filed separately with the Secretary of the Commission without redactions pursuant to our Application Requesting Confidential Treatment under the Securities Exchange Act of 1934.

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: November 2, 2012

By: /s/ Robert S. Vaters
Name: Robert S. Vaters
Title: President and Chief Executive Officer

Date: November 2, 2012

By: /s/ Brian McCollum
Name: Brian McCollum
Title: Senior Vice President of Finance and Chief Financial Officer