

ORTHOFIX INTERNATIONAL N V
Form 10-Q
July 30, 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 June 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.

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

(Exact name of registrant as specified in its charter)

Curaçao
(State or other jurisdiction of
incorporation or organization)

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

7 Abraham de Veerstraat

Curaçao
(Address of principal executive offices)

Not applicable
(Zip Code)

599-9-4658525

(Registrant's telephone number, including area code)

Not applicable

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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

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

As of July 26, 2012, 18,968,031 shares of common stock were issued and outstanding.

Table of Contents**Table of Contents**

	Page
<u>PART I</u>	
<u>FINANCIAL INFORMATION</u>	3
<u>Item 1.</u>	3
<u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of June 30, 2012 (unaudited) and December 31, 2011</u>	3
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2012 and 2011 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2012 and 2011 (unaudited)</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
<u>Item 2.</u>	21
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3.</u>	28
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
<u>Item 4.</u>	28
<u>Controls and Procedures</u>	28
<u>PART II</u>	29
<u>OTHER INFORMATION</u>	29
<u>Item 1.</u>	29
<u>Legal Proceedings</u>	29
<u>Item 1A.</u>	33
<u>Risk Factors</u>	33
<u>Item 6.</u>	35
<u>Exhibits</u>	35
<u>SIGNATURES</u>	39

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, 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 the government investigation and False Claims Act matter relating to our spinal implant business, court review and approvals of our pending settlements in certain government litigation matters, 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

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

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)	June 30, 2012 (unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 50,089	\$ 33,207
Restricted cash	72,913	45,476
Trade accounts receivable, less allowance for doubtful accounts of \$11,072 and \$9,376 at June 30, 2012 and December 31, 2011, respectively	149,472	132,828
Inventories, net	78,423	82,969
Deferred income taxes	20,106	16,349
Escrow receivable		41,537
Prepaid expenses and other current assets	25,386	26,069
Assets held for sale		171,185
Total current assets	396,389	549,620
Property, plant and equipment, net	45,267	43,368
Patents and other intangible assets, net	7,294	8,236
Goodwill	73,111	73,094
Deferred income taxes	18,444	18,584
Other long-term assets	12,815	11,570
Total assets	\$ 553,320	\$ 704,472
Liabilities and shareholders equity		
Current liabilities:		
Bank borrowings	\$ 499	\$ 1,318
Current portion of long-term debt		17,500
Trade accounts payable	11,551	16,488
Accrued charges related to U.S. Government resolutions	83,864	82,500
Other current liabilities	50,132	45,327
Liabilities held for sale		22,676
Total current liabilities	146,046	185,809
Long-term debt	40,000	191,195
Deferred income taxes	9,781	9,778
Other long-term liabilities	3,277	2,519
Total liabilities	199,104	389,301
Contingencies (Note 16)		
Shareholders equity:		
Common shares \$0.10 par value; 50,000,000 shares authorized; 18,946,481 and 18,465,444 issued and outstanding as of June 30, 2012 and December 31, 2011, respectively	1,895	1,846

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

Additional paid-in capital	231,758	214,310
Retained earnings	120,475	97,254
Accumulated other comprehensive income	88	1,761
Total shareholders' equity	354,216	315,171
Total liabilities and shareholders' equity	\$ 553,320	\$ 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 six months ended June 30, 2012 and 2011**

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net sales	\$ 119,492	\$ 116,670	\$ 235,534	\$ 229,731
Cost of sales	23,676	23,186	45,616	45,527
Gross profit	95,816	93,484	189,918	184,204
Operating expenses				
Sales and marketing	49,810	49,960	99,331	97,399
General and administrative	14,295	17,344	28,865	36,130
Research and development	9,252	6,229	16,302	11,673
Amortization of intangible assets	530	555	1,060	1,103
Charges related to U.S. Government resolutions (Note 16)	1,364		1,364	46,000
	75,251	74,088	146,922	192,305
Operating income (loss)	20,565	19,396	42,996	(8,101)
Other income and expense				
Interest expense, net	(1,265)	(2,198)	(3,486)	(4,613)
Other income (expense), net	660	(342)	29	(1,451)
	(605)	(2,540)	(3,457)	(6,064)
Income (loss) before income taxes	19,960	16,856	39,539	(14,165)
Income tax expense	(5,993)	(6,337)	(13,356)	(12,056)
Net income (loss) from continuing operations, net of tax	13,967	10,519	26,183	(26,221)
Discontinued operations (Note 15)				
Gain on sale of Breg, Inc., net of tax	1,040		1,040	
Income (loss) from discontinued operations	(5,846)	(796)	(6,352)	676
Income tax benefit (expense)	2,044	235	2,350	(298)
Net income (loss) from discontinued operations, net of tax	(2,762)	(561)	(2,962)	378
Net Income (loss)	\$ 11,205	\$ 9,958	\$ 23,221	\$ (25,843)
Net income (loss) per common share- basic:				
Net income (loss) from continuing operations, net of tax	\$ 0.74	\$ 0.58	\$ 1.40	\$ (1.45)
Net income (loss) from discontinued operations, net of tax	(0.15)	(0.03)	(0.16)	0.02
Net income (loss) per common share- basic	\$ 0.59	\$ 0.55	\$ 1.24	\$ (1.43)
Net income (loss) per common share- diluted:				
Net income (loss) from continuing operations, net of tax	\$ 0.73	\$ 0.57	\$ 1.37	\$ (1.45)
Net income (loss) from discontinued operations, net of tax	(0.15)	(0.03)	(0.16)	0.02
Net income (loss) per common share- diluted:	\$ 0.58	\$ 0.54	\$ 1.21	\$ (1.43)
Weighted average number of common shares:				
Basic	18,827,452	18,110,607	18,751,573	18,024,913
Diluted	19,215,984	18,541,220	19,168,940	18,024,913
Comprehensive income (loss)	\$ 6,822	\$ 11,793	\$ 21,548	\$ (20,918)

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 six months ended June 30, 2012 and 2011**

(Unaudited, U.S. Dollars, in thousands)	Six Months Ended June 30,	
	2012	2011
Cash flows from operating activities:		
Net income (loss)	\$ 23,221	\$ (25,843)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	11,018	11,324
Amortization of debt costs	1,375	643
Provision for doubtful accounts	5,324	4,545
Deferred income taxes	(1,653)	(2,680)
Share-based compensation	3,000	3,997
Provision for inventory obsolescence	836	2,116
Gain on sale of Breg, Inc.	(1,040)	
Excess tax benefit on non-qualified stock options	(1,156)	(1,004)
Other	(6,060)	335
Change in operating assets and liabilities, net of effect of disposition:		
Trade accounts receivable	(24,437)	(5,353)
Inventories	2,247	(12,423)
Escrow receivable	41,537	(326)
Prepaid expenses and other current assets	335	3,704
Trade accounts payable	(4,391)	(2,312)
Charges related to U.S. Government resolutions	1,364	46,000
Other current liabilities	6,236	680
Net cash provided by operating activities	57,756	23,403
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(12,794)	(10,963)
Capital expenditures for intangible assets	(214)	(335)
Payment made in connection with acquisition		(5,250)
Net proceeds from the sale of Breg, Inc.	153,092	
Net cash provided by (used in) investing activities	140,084	(16,548)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	13,341	13,453
Repayments of long-term debt	(168,695)	(2,500)
Payment of refinancing fees		(758)
Repayment of bank borrowings, net	(831)	(1,653)
Changes in restricted cash	(25,831)	(2,285)
Cash payment for purchase of minority interest in subsidiary		(517)
Excess tax benefit on non-qualified stock options	1,156	1,004
Net cash (used in) provided by financing activities	(180,860)	6,744
Effect of exchange rate changes on cash	(98)	325
Net increase in cash and cash equivalents	16,882	13,924

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

Cash and cash equivalents at the beginning of the period		33,207		13,561
Cash and cash equivalents at the end of the period	\$	50,089	\$	27,485

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. Description of business

Orthofix International N.V. (the Company) is a diversified, global medical device company focused on developing and delivering innovative repair and regenerative technologies to the spine and orthopedic markets. The Company is comprised of two reportable segments: Spine and Orthopedics that are supported by Corporate activities.

On May 24, 2012 (the Closing Date of the Transaction), Orthofix Holdings Inc. (Orthofix Holdings) completed the sale of all of the outstanding shares of Breg, Inc (Breg) for \$157.5 million in cash. Beginning June 30, 2012, the former sports medicine business is presented as discontinued operations for all periods. As a result of the sale of Breg, the Company completed its exit from the Sports Medicine global business unit (GBU), of which Breg was a significant component. The operations and cash flows of the former Sports Medicine GBU have been eliminated from the ongoing operations, and there is no significant continuing involvement in the sold business. See Note 15 for detailed information on the discontinued operations.

2. Summary of significant accounting policies

(a) Basis of presentation

The accompanying Unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S.) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures, normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S., have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 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)****3. 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)	June 30, 2012	December 31, 2011
Raw materials	\$ 8,017	\$ 10,115
Work-in-process	5,874	5,606
Finished products	44,244	49,141
Field inventory	38,954	39,400
Consignment inventory	7,317	7,551
	104,406	111,813
Less reserve for obsolescence	(25,983)	(28,844)
	\$ 78,423	\$ 82,969

4. Patents and other intangible assets

(US\$ in thousands)	June 30, 2012	December 31, 2011
Cost		
Patents and developed technologies	\$ 32,480	\$ 37,683
Trademarks – definite lived (subject to amortization)	548	545
	33,028	38,228
Accumulated amortization		
Patents and developed technologies	(25,339)	(29,611)
Trademarks – definite lived (subject to amortization)	(395)	(381)
Patents and other intangible assets, net	\$ 7,294	\$ 8,236

Amortization expense for intangible assets is estimated to be approximately \$1 million for the remainder of 2012 and \$2 million, \$1.3 million, \$1.3 million, \$0.9 million and \$0.8 million for the periods ending December 31, 2013, 2014, 2015, 2016 and 2017 and thereafter, respectively.

5. Goodwill

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

(US\$ in thousands)		Total
At December 31, 2011	\$	73,094
Foreign currency		17
At June 30, 2012	\$	73,111

Table of Contents

Notes to the Unaudited Condensed Consolidated Financial Statements (continued)

6. Bank borrowings

Borrowings under lines of credit consist of borrowings in Euros used to fund international operations. The borrowings under such facilities were \$0.5 million and \$1.3 million at June 30, 2012 and December 31, 2011, respectively. The weighted average interest rates on borrowings under lines of credit as of June 30, 2012 and December 31, 2011 were 3.41% and 4.02%, respectively.

The Company had an unused available line of credit of 6.9 million (\$8.7 million) and 6.3million (\$8.1 million) at June 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.

7. Long-term debt

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

The Credit Agreement provides for a five year, \$200.0 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, the Company used a portion of the proceeds from the sale of Breg, Inc. (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. In June 2012, the Company paid down an additional \$20 million of amounts outstanding under the Revolving Credit Facility. As a result, at June 30, 2012, the Term Loan Facility had been repaid in full and there was \$40 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 June 30, 2012, the entire Revolving Credit Facility was at the LIBOR rate plus a margin of 3.00%. 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 June 30, 2012 and December 31, 2011 was 3.3% 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.

In May 2011, the Company obtained an amendment to the Credit Agreement to provide additional capacity under the various restrictive negative covenants for the Company's payment of the Specified Settlement Amounts (as defined in the Credit Agreement, as amended) associated with each of the potential settlements (See Note 16). 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 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 June 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 June 30, 2012 and December 31, 2011 was \$200 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 restricted cash of the Company as of June 30, 2012 and December 31, 2011 was \$72.9 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 June 30, 2012 and December 31, 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were \$2.1 million and \$3.5 million, respectively.

8. Derivative instruments

The tables below disclose the types of derivative instruments the Company owns, the classifications and fair values of these instruments within the balance sheet, and the amount of gain (loss) recognized in other comprehensive income (loss) (OCI) or net income (loss).

(US\$ in thousands)	Fair value: favorable (unfavorable)		Balance sheet location	
As of June 30, 2012				
Cross-currency swap	\$	2,321	Other long-term assets	
As of December 31, 2011				
Cross-currency swap	\$	1,011	Other long-term assets	
(US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Cross-currency swap unrealized gain (loss) recorded in other comprehensive income (loss), net of taxes	\$ (585)	\$ 199	\$ (76)	\$ 1,301

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.

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

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 7), 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)****9. Fair value measurements**

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Non-financial assets and liabilities of the Company measured at fair value include any long-lived assets or equity method investments that are impaired in a currently reported period. The authoritative guidance also describes three levels of inputs that may be used to measure fair value:

Level 1	quoted prices in active markets for identical assets and liabilities
Level 2	observable inputs other than quoted prices in active markets for identical assets and liabilities
Level 3	unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

As of June 30, 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 June 30, 2012 because our interest rate was at the one month LIBOR plus an applicable margin. See Note 7 for further discussion of our Credit Facilities.

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 June 30, 2012	Level 1	Level 2	Level 3
Derivative financial instruments (1)				
Cash flow hedges				
Cross-currency hedge	\$ 2,321	\$	\$ 2,321	\$

(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)****10. Comprehensive income (loss)**

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and the effective portion of the gain (loss) on the Company's cross-currency swap, which is designated and accounted for as a cash flow hedge (See Note 8). 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 \$(44)		(76)	(76)
Foreign currency translation adjustment (1)	(1,597)		(1,597)
Balance at June 30, 2012	\$ 296	\$ (208)	\$ 88

(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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net income (loss)	\$ 11,205	\$ 9,958	\$ 23,221	\$ (25,843)
Other comprehensive income (loss):				
Unrealized gain (loss) on cross-currency swap, net of tax	(585)	199	(76)	1,301
Foreign currency translation adjustment	(3,798)	1,636	(1,597)	3,624
Total comprehensive income (loss)	\$ 6,822	\$ 11,793	\$ 21,548	\$ (20,918)

11. Earnings per share

For the three and six months ended June 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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Weighted average common shares-basic	18,827,452	18,110,607	18,751,573	18,024,913
Effect of dilutive securities:				
Unexercised stock options net of treasury share repurchase	388,532	430,613	417,367	
Weighted average common shares-diluted	19,215,984	18,541,220	19,168,940	18,024,913

No adjustment has been made in the six months ended June 30, 2011 for any common stock equivalents because their effects would be anti-dilutive. For the six months ended June 30, 2011, potentially dilutive shares totaled 350,233.

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 796,851 and 768,269 outstanding options not included in the diluted earnings per share computation for the three and six months ended June 30, 2012, respectively, because the inclusion of these options was anti-dilutive. There were 1,601,560 and 1,594,274 outstanding options not included, respectively, in the diluted earnings per share computation for the three and six months ended June 30, 2011, respectively, because the inclusion of these options was anti-dilutive.

Table of Contents**Notes to the Unaudited Condensed Consolidated Financial Statements (continued)****12. Share-based compensation**

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

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

(US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30, 2011	
	2012	2011	2012	2011
Cost of sales	\$ 106	\$ 35	\$ 283	\$ 72
Sales and marketing	397	511	842	1,110
General and administrative	772	1,777	1,542	2,489
Research and development	30	49	71	97
Total	\$ 1,305	\$ 2,372	\$ 2,378	\$ 3,768

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

During the three and six months ended June 30, 2012, there were 218,324 and 481,037 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 six months ended June 30, 2011, there were 218,831 and 515,318 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

13. Income taxes*Continuing Operations*

The Company recognized a \$13.4 million and \$12.1 million provision for income tax on continuing operations which reflects an effective tax rate of 33.8% on pre-tax income and (85.1%) on a pre-tax loss for the six months ended June 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 six months of 2012 and 2011 was 37.0% and 37.9%, respectively. The principal factors affecting the Company's effective tax rate for the first six 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

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

effective tax rate for the first six 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.

Discontinued Operations

The Company recognized a \$2.4 million benefit and \$0.3 million provision for income tax on discontinued operations which reflect an effective tax rate of 44.2% on a pre-tax loss and 44.0% on a pre-tax income for the six months ended June 30, 2012 and 2011, respectively. The effective tax rate on discontinued operations for the first six months of 2012 was 37.0% excluding the impact of the gain on the sale of Breg, Inc. in 2012. The principal factors affecting the Company's effective tax rate for the first six months of 2012 and 2011 were the tax benefit of discrete items, 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.

As of June 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 June 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 June 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, 2008. 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)

14. Business segment information

The Company's segment information is prepared on the same basis that management reviews the financial information for operational decision making purposes. At this time, the Company's 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. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. The Company manages its business by its two GBUs, which are comprised of Spine and Orthopedics supported by Corporate activities. These GBUs represent the segments for which the CODM reviews financial information and makes resource allocation decisions among business units. Accordingly, the Company's segment information (as provided below) has been prepared based on the Company's two GBUs reporting segments. These 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 the Company's spinal 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.

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 the Company's 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.

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

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

(US\$ in thousands)	External Net Sales by GBU Three Months Ended June 30,			
	2012	2011	Reported Growth	Constant Currency Growth
Spine				
Spine Repair Implants and Regenerative Biologics	\$ 38,501	\$ 36,882	4%	4%
Spine Regenerative Stimulation	43,294	39,660	9%	9%
Total Spine	81,795	76,542	7%	7%
Orthopedics	37,697	40,128	(6)%	2%
Total Net Sales	\$ 119,492	\$ 116,670	2%	5%

Spine				
Spine Regenerative Stimulation	82,565	78,278	5%	5%
Total Spine	156,823	149,117	5%	5%
Orthopedics	78,711	80,614	(2)%	3%
Total Net Sales	\$ 235,534	\$ 229,731	3%	4%

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 segments:

Operating Income (Loss) by GBU (US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Spine (1)	\$ 21,029	\$ 22,292	\$ 42,594	\$ 5,866
Orthopedics (2)	4,093	4,972	9,073	1,340
Corporate (3)	(4,557)	(7,868)	(8,671)	(15,307)
Total	\$ 20,565	\$ 19,396	\$ 42,996	\$ (8,101)

(1) For the six months ended June 30, 2012 and 2011, the operating income for the Spine GBU included \$1.2 million and \$36.5 million, respectively, of expenses in connection with charges related to U.S. Government resolutions. For the six months ended June 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.

(2) For the six months ended June 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.

(3) For the six months ended June 30, 2011, the operating loss for the Corporate GBU included \$3 million of expenses in connection with charges related to U.S. Government resolutions. For the three and six months ended June 30, 2011, the operating loss for the Corporate GBU included \$3.2 million of senior management succession charges.

15. Sale of Breg and Disposition of Sports Medicine GBU

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

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

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 \$2 million as of June 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 June 30, 2012.

(US\$ in thousands)	Total
Cash proceeds	\$ 157,500
Less:	
Working Capital	(7,532)
Transaction related expenses	(4,057)
Fair Value of Indemnification	(2,000)
Tangible assets	(8,292)
Intangible assets	(28,164)
Goodwill	(106,200)
Gain on sale of Breg	1,255
Income tax expense	(215)
Gain on sale of Breg, net of taxes	\$ 1,040

The Sports Medicine GBU contributed \$43.4 million and \$53 million of net sales in the six months ended June 30, 2012 and 2011, respectively. The Sports Medicine global business unit contributed \$16.3 million and \$26.9 million of net sales in the three months ended June 30, 2012 and 2011, respectively. The Sports Medicine global business unit had \$2.9 million of operating loss and \$0.6 million of operating income in the six months ended June 30, 2012 and 2011, respectively. The Sports Medicine global business unit had \$2.5 million and \$0.8 million of operating loss in the three months ended June 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 global business unit as discontinued operations. Income (loss) associated with the Sports Medicine global business unit, 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

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

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)

16. Contingencies

The Company is a party to outstanding legal proceedings, investigations and claims as described below. The Company believes that it is unlikely that the outcome of each of these matters, including the matters discussed below, 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 legal proceedings, investigations (including any settlement discussions with the government seeking to resolve such investigations) or claims made against it or its subsidiaries described in the paragraphs 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 described 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

Matters Related To Blackstone Medical, Inc. and Related Escrow Claims

On or about July 23, 2007, the Company's subsidiary, Blackstone Medical, Inc. ("Blackstone") received a subpoena issued by the Office of Inspector General of the Department of Health and Human Services ("HHS-OIG"), under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena sought documents for the period January 1, 2000 through July 31, 2006, which is prior to Blackstone's acquisition by the Company. The Company believes that the subpoena concerned the compensation of physician consultants and related matters. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between the Company, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the "Blackstone Merger Agreement"), for any losses to the Company resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders of Blackstone that the representative of the former shareholders of Blackstone objected to the indemnification claim and intended to contest it in accordance with the terms of the Blackstone Merger Agreement.

Table of Contents

Notes to the Unaudited Condensed Consolidated Financial Statements (continued)

On or about January 7, 2008, the Company received a federal grand jury subpoena from the U.S. Attorney's Office for the District of Massachusetts (Boston USAO). The subpoena sought documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerned the compensation of physician consultants and related matters, and further believes that it was associated with HHS-OIG's investigation of such matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On or about April 29, 2009, counsel received a HIPAA subpoena issued by the U.S. Department of Justice (DOJ). The subpoena sought documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerned the compensation of physician consultants and related matters, and further believes that it was associated with HHS-OIG's investigation of such matters, as well as the January 7, 2008 federal grand jury subpoena. On or about August 26, 2010, counsel for Orthofix Inc. and Blackstone executed a tolling agreement with the Boston USAO (the Tolling Agreement) that extended an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate to include the period from December 1, 2008 through and including October 31, 2010. On or about February 1, 2011, the parties further extended the tolling of the statute of limitations through and including May 31, 2011 with respect to any criminal proceedings that the government might later initiate.

On or about December 5, 2008, the Company obtained a copy of a qui tam complaint filed by Susan Hutcheson and Philip Brown against Blackstone and the Company in the U.S. District Court for the District of Massachusetts. A qui tam action is a civil lawsuit brought by an individual for an alleged violation of a federal statute, in which DOJ has the right to intervene and take over the prosecution of the lawsuit at its option. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of DOJ and prior to the unsealing of the complaint (which was unsealed by the court on or about November 24, 2008), the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On November 21, 2008, the U.S. Department of Justice filed a notice of non-intervention in the case. The complaint was served on Blackstone on or about March 24, 2009. Counsel for the plaintiffs filed an amended complaint on June 4, 2009. The amended complaint sets forth a cause of action against Blackstone under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants; Orthofix is not named as a defendant in the amended complaint. The Company understands that this lawsuit was related to the matters described above involving the HHS-OIG, the Boston USAO, and DOJ. On or about March 12, 2010, the United States District Court for the District of Massachusetts granted Blackstone's motion to dismiss and, on March 15, 2010, entered judgment in favor of Blackstone. On June 1, 2011, the United States Court of Appeals for the First Circuit reversed the motion to dismiss and remanded to the district court for further proceedings. In response to a joint motion to stay the action, on August 22, 2011, the United States District Court for the District of Massachusetts entered an order administratively closing the lawsuit for a period of no more than ninety (90) days. On August 30, 2011, Blackstone filed with the United States Supreme Court a Petition for a Writ of Certiorari to review the June 1, 2011 judgment of the United States Court of Appeals for the First Circuit, which was denied on December 5, 2011.

In January 2012, after a series of ongoing discussions and negotiations with the Boston USAO, the Company's board of directors approved an agreement in principle to pay \$32 million to resolve the matters described in the immediately preceding paragraphs. The Company is currently in discussions with the Boston USAO, the DOJ, and HHS-OIG, as to the terms of definitive written agreements to finally resolve these matters. As part of the resolution of this matter (and matters described below related to the Company's regenerative stimulation business), on June 6, 2012, Orthofix International N.V., Orthofix Inc. and Blackstone Medical, Inc. entered into a five-year Corporate Integrity Agreement with HHS-OIG. (The Corporate Integrity Agreement is further described below under the subheading Corporate Integrity Agreement with HHS-OIG .) Based on information currently available, the Company believes that it is probable that a final written definitive settlement agreement with the U.S. Government will be entered into on these economic terms, which, as described below, would be fully funded from the escrow fund established in connection with the Blackstone Merger Agreement. There can be no assurance that the Company will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, the Company believes that the likelihood of any such additional material loss in excess of this amount is remote.

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

In 2007 and 2008, the Company received certain other subpoenas from state and federal entities related to Blackstone's financial relationship with physicians, which the Company has described in prior reports. The Company has fully responded to each of these subpoenas, and there are currently no pending proceedings related to any of these matters.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone agreed to indemnify the Company for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders were limited to a cumulative aggregate amount of \$66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was \$50.0 million. As of December 31, 2011, the escrow fund contained \$47.5 million.

Table of Contents

Notes to the Unaudited Condensed Consolidated Financial Statements (continued)

In February 2012, the Company reached an agreement with the representative of the former shareholders of Blackstone resolving all outstanding escrow and indemnification claims under the Blackstone Merger Agreement. Under this agreement, approximately \$42.5 million was distributed from the escrow fund to the Company (which will be used, among other things, to fund the proposed \$32 million settlement in principle described above). Each of the Company and the former shareholders of Blackstone also mutually released each other from all further claims against each other related to these matters. As of September 30, 2011, the Company had recognized \$15.5 million as an escrow receivable on the consolidated balance sheet, reflecting previously incurred expenses that the Company believed were reasonably assured of collection. The Company received approximately \$9.5 million in cash from the escrow fund after application of (i) the \$32 million allocated to the settlement in principle described above with the government and (ii) approximately \$1 million of other fees incurred with respect to this matter since September 30, 2011. As a result, the Company recorded a charge of approximately \$6 million during the fourth quarter of 2011 for previously incurred legal fees that were reflected in this escrow receivable balance as of September 30, 2011. The Company recorded a charge of \$0.2 million in the second quarter of 2012 which represents imputed interest on the settlement accrued through June 30, 2012.

Matters Related to Regenerative Stimulation Business

On or about April 10, 2009, the Company received a HIPAA subpoena (HIPAA subpoena) issued by the Boston USAO. The subpoena sought documents concerning, among other things, the Company's promotion and marketing of its regenerative stimulator devices (which the Company has also described in the past as its bone growth stimulator devices). The Boston USAO issued several subsequent document and testimony subpoenas. The Company cooperated with these requests.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the U.S. District Court for the District of Massachusetts against the Company, Orthofix Inc. and other companies that have allegedly manufactured regenerative stimulation devices, including Orthologic Corp., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. The complaint, as subsequently amended in 2010, alleged various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of regenerative stimulation devices. The complaint also included claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-Kickback Act by providing free products to physicians, waiving patients' insurance co-payments and providing inducements to independent sales agents to generate business.

On April 28, 2011, after a series of ongoing discussions and negotiations with the Boston USAO, the Company's board of directors approved an agreement in principle proposed by the Boston USAO to resolve the criminal and civil matters described in the immediately preceding two paragraphs. On June 6, 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 Mr. Bierman. This settlement agreement finally resolves these matters.

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 on June 7, 2012 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 a charge of \$1.2 million in the second quarter of 2012 which represents imputed interest on the settlement accrued through June 30, 2012.

The settlement is neither an admission of liability by the Company or its subsidiaries nor a concession by the United States or the civil qui tam relator that their claims are not well founded, except as to such admissions as Orthofix Inc. makes in connection with its guilty plea under the Plea Agreement.

Table of Contents

Notes to the Unaudited Condensed Consolidated Financial Statements (continued)

Corporate Integrity Agreement with HHS-OIG

On June 6, 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 a final settlement of the government investigation and related qui tam complaint described above related to Blackstone Medical, Inc., the Company also entered into a five-year corporate integrity agreement with HHS-OIG (the "CIA"). The CIA acknowledges the existence of the Company's current compliance program, and requires that the Company continue to maintain during the term of the CIA a compliance program designed to promote compliance with federal healthcare and Food and Drug Administration ("FDA") requirements. The Company is also required to maintain several elements of the existing program during the term of the CIA, including maintaining a Chief Compliance Officer, a Compliance Committee, and a Code of Conduct. The CIA requires that the Company conduct certain additional compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations. Pursuant to the CIA, the Company is required to notify the HHS-OIG in writing, among other things, of: (i) any ongoing government investigation or legal proceeding involving an allegation that the Company has committed a crime or has engaged in fraudulent activities; (ii) any other matter that a reasonable person would consider a probable violation of applicable criminal, civil, or administrative laws related to compliance with Federal healthcare programs or FDA requirements; and (iii) any change in location, sale, closing, purchase, or establishment of a new business unit or location related to items or services that may be reimbursed by Federal healthcare programs. The Company is also subject to periodic reporting and certification requirements attesting that the provisions of the CIA are being implemented and followed, as well as certain document and record retention mandates. The CIA provides that in the event of an uncured material breach of the CIA, the Company could be excluded from participation in Federal healthcare programs and/or subject to monetary penalties.

Matters Related to Promeca

During the second quarter of 2010 internal management review of Promeca S.A. de C.V. ("Promeca"), one of the Company's Mexican subsidiaries, the Company received allegations of improper payments by certain of Promeca's local employees in Mexico to employees of a Mexican governmental healthcare entity. The Company engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation (the "Promeca Internal Investigation") focusing on compliance with the Foreign Corrupt Practices Act ("FCPA") and voluntarily contacted the Securities and Exchange Commission (the "SEC") and DOJ to advise both agencies that an internal investigation was underway. Promeca accounted for approximately one percent of the Company's consolidated net sales and consolidated total assets.

The Company completed the Promeca Internal Investigation in April 2011 and commenced settlement discussions with the U.S. Government regarding this matter in May 2011. In January 2012, the Company reached an agreement in principle to settle these matters with the DOJ, and on July 10, 2012, the Company entered into definitive agreements with DOJ and the SEC agreeing to settle this matter. As part of the settlement, the Company has entered into (i) a consent to final judgment (the "SEC Consent") with the SEC in a civil matter filed by the SEC on the same date in the U.S. District Court for the Eastern District of Texas and (ii) a deferred prosecution agreement (the "DPA") with DOJ. These agreements remain subject to review and approval by the U.S. District Court for the Eastern District of Texas, and there can be no assurance that they will be approved by the court on the terms proposed.

Under the terms of the SEC Consent, the Company will settle 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 has also agreed to pay a fine of \$2.2 million to the U.S. Government pursuant to the terms of the DPA. The Company previously recorded charges of \$3.0 million during the first quarter of

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

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 DOJ and the SEC. The Company made payment of the amounts owed pursuant to the DPA in July 2012, and expects to make payments pursuant to the SEC Consent in the third fiscal quarter of 2012.

As part of the DPA, which has a term of three years, DOJ has agreed not to pursue any criminal charges against the Company in connection with this matter if the Company complies with the terms of the DPA. The DPA takes note of the Company's self-reporting of this matter to DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by the Company.

The DPA provides that the Company shall continue to cooperate fully with DOJ in any future matters related to corrupt payments, false books and records or inadequate internal controls. In that regard, the Company has represented that the Company has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws.

The Company will periodically report to DOJ during the term of the DPA regarding such remediation and implementation of compliance measures.

In addition, under the terms of the SEC Consent, the Company will periodically report to the SEC during a two-year term regarding the status of such remediation and implementation of compliance measures. The SEC Consent and the DPA do not provide for the appointment of any independent external monitor by DOJ or the SEC.

Table of Contents

Notes to the Unaudited Condensed Consolidated Financial Statements (continued)

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 the July 2012 verdict described in the preceding paragraph, however, actual liability in this case could be higher or lower than the amount accrued. 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.

The Company's former subsidiary, Breg, which the Company divested in May 2012, was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008. Since 2008, numerous product liability cases have been filed in the United States alleging that the local anesthetic, when dispensed by such infusion pumps inside a joint, causes a rare arthritic condition called chondrolysis. The Company believes that meritorious defenses exist to these claims and Breg is vigorously defending these cases. One of the Company's insurance carriers has asserted to the Company that certain potential losses related to this matter are not covered by its insurance coverage, and the Company currently is in arbitration with this carrier.

On or about August 2, 2010, Breg received a HIPAA subpoena issued by the DOJ. The subpoena seeks documents from the Company and its subsidiaries for the period of January 1, 2000 through the date of the subpoena. The Company believes that document production in response to the subpoena is completed as of July 2012. The Company believes that this subpoena relates to an investigation by the DOJ into whether Breg's sale, marketing and labeling of local infusion pumps for pain management, prior to Breg's divestiture of this product line in 2008, complied with FDA regulations and federal law. On January 27, 2012, the Company was orally notified by a U.S. Government official that a civil investigation of Breg was pending in connection with this matter. The Company is currently cooperating with the U.S. Government in connection with this matter.

At the time of its divestiture by the Company, Breg was currently and had been engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases have been filed in recent years, mostly in California state court, alleging that the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units. The majority of these cases are at an early stage and no conclusion can be drawn at the present time regarding their potential outcome. However, the Company believes that meritorious defenses exist to these claims. In July 2012, a jury in one case returned a verdict providing for approximately \$2.0 million in compensatory damages to the plaintiff against Breg, and could assess additional exemplary damages in the future. The Company expects the \$2.0 million compensatory award to be covered by existing insurance policies, while any exemplary portion of an award will not be covered by insurance. The case remains subject to further post-verdict motions and appeals.

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 six months ended June 30, 2012 compared to our results of operations for the three and six months ended June 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 (as provided below) has been prepared based on our two GBU 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 global business unit for the three and six months ended June 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 June 30,			
	2012	2011	Reported Growth	Constant Currency Growth
Spine				
Spine Repair Implants and Regenerative Biologics	\$ 38,501	\$ 36,882	4%	4%
Spine Regenerative Stimulation	43,294	39,660	9%	9%
Total Spine	81,795	76,542	7%	7%
Orthopedics	37,697	40,128	(6)%	2%
Total Net Sales	\$ 119,492	\$ 116,670	2%	5%

Table of Contents

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012 (%)	2011 (%)	2012 (%)	2011 (%)
Net sales	100	100	100	100
Cost of sales	20	20	19	20
Gross profit	80	80	81	80
Operating expenses:				
Sales and marketing	42	43	42	42
General and administrative	12	15	12	16
Research and development	8	5	7	5
Amortization of intangible assets	0	0	0	0
Charges related to U.S. Government inquiries	1	0	1	20
Operating income (loss)	17	17	18	(4)
Net income (loss)	9	9	10	(11)

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

Net sales increased \$2.8 million to \$119.5 million in the second quarter of 2012 compared to \$116.7 million for the same period last year. The impact of foreign currency decreased sales by \$3.3 million during the second quarter of 2012 when compared to the second quarter of 2011.

Sales

Net sales in our Spine global business unit increased to \$81.8 million in the second quarter of 2012 compared to \$76.5 million for the same period last year, an increase of \$5.3 million. The increase in Spine's net sales was primarily the result of a 9% 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 second quarter of 2012 increased 4% when compared to the same period in the prior year, due to increased adoption of Trinity ® Evolution in spine applications which led to a 48% increase in sales of Regenerative Biologics in the second quarter of 2012.

Net sales in our Orthopedics global business unit decreased 6%, (but increased 2% on a constant currency basis) to \$37.7 million in the second quarter of 2012 compared to \$40.1 million for the same period last year. This constant currency increase was led by sales of Regenerative Biologics in Orthopedics applications resulting in a 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 \$2.3 million to \$95.8 million in the second quarter of 2012 compared to \$93.5 million for the same period last year. Gross profit as a percent of net sales in the second quarter of 2012 was 80.2% for the second quarter of 2012 and 80.1% for 2011 during the same period.

Sales and Marketing Expense Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense decreased \$0.2 million, to \$49.8 million in the second quarter of 2012 compared to \$50 million in the second quarter of 2011. As a percent of net sales, sales and marketing expense was 41.7% and 42.8% in the first quarter of 2012 and 2011, respectively. The second quarter of 2011 also included \$0.3 million of senior management succession charges.

General and Administrative Expense General and administrative expense decreased \$3 million, or 17%, in the second quarter of 2012 to \$14.3 million compared to \$17.3 million in the second quarter of 2011. The second quarter of 2011 included \$3.2 million of senior management succession charges. We incurred \$0.4 million and \$1.6 million of expenses in the second 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% in the second quarter of 2012 compared to 14.9% for the same period last year.

Research and Development Expense Research and development expense increased \$3.1 million in the second quarter of 2012 to \$9.3 million compared to \$6.2 million in the second quarter of 2011. The increase in research and development expenses in the second quarter of 2012 compared to the same period in the prior year was due to a \$3.1 million charge, or 2.6% of net sales, for an arbitration resolution related to a 2008 co-development agreement. As a percent of sales, research and development expense was 7.7% in the second quarter of 2012 compared to 5.3% for the same period last year.

Table of Contents

Amortization of Intangible Assets Amortization of intangible assets decreased by \$0.1 million in the second quarter of 2012 to \$0.5 million compared to \$0.6 million for the same period last year.

Charges Related to U.S. Government Resolutions The Company recorded a charge of \$1.4 million in the second 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., respectively.

Interest Expense, net Interest expense, net was \$1.3 million for the second quarter of 2012 compared to \$2.2 million for the same period last year, primarily as the result of a lower year over year outstanding debt balance repaid with a portion of the proceeds from the sale of Breg.

Other Income and Expense Other income (expense) was \$0.7 million and (\$0.3) million for the second quarters 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 30.0% and 37.6% during the second quarters of 2012 and 2011, respectively. The effective tax rate for the second 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 second quarter of 2012 rate was also affected by the tax benefit of discrete items related to the U.S. Government resolutions. The effective tax rate for the second quarter of 2012 was 36.5% excluding the impact of the discrete charges.

Discontinued operations Discontinued operations in the second quarter of 2012 and 2011 includes the results of our Sports Medicine GBU up to May 24, 2012 (the closing date of the sale of Breg), net of income taxes. The second quarter of 2012 also includes the gain on the sale of Breg, of \$1.3 million, net of income taxes of \$0.2 million.

Net Income Net income for the second quarter of 2012 was \$11.2 million, or \$0.59 per basic and \$0.58 per diluted share, compared to net income of \$10 million, or \$0.55 per basic share and \$0.54 per diluted share for the same period last year.

Six Months Ended June 30, 2012 Compared to Six Months Ended June 30, 2011

Net sales increased \$5.8 million to \$235.5 million in the first six months of 2012 compared to \$229.7 million for the same period last year. The impact of foreign currency decreased sales by \$4.5 million during the first six months of 2012 when compared to the same period of 2011.

Sales

Net sales in our Spine global business unit increased to \$156.8 million in the first six months of 2012 compared to \$149.1 million for the same period last year, an increase of \$7.7 million. The increase in Spine's net sales was primarily the result of a 5% increase in sales of our Repair and Regenerative biologics revenue products in the first six 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 48% increase in sales of Regenerative Biologics in the first six months of 2012. The Regenerative Stimulation products used in Spine applications increased 5% when compared to the prior year.

Net sales in our Orthopedics global business unit decreased 2%, (but increased 3% on a constant currency basis) to \$78.7 million in the first six months of 2012 compared to \$80.6 million for the same period last year. The constant currency sales growth was led by sales of Trinity® Evolution in Orthopedic applications resulted in an 11% 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 \$5.7 million to \$189.9 million in the first six months of 2012, compared to \$184.2 million for the same period last year. Gross profit as a percent of net sales in the first six months of 2012 was 80.6% for the first six months of 2012 and 80.2% in 2011 during the same period.

Sales and Marketing Expense Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$1.9 million, to \$99.3 million in the first six months of 2012 compared to \$97.4 million in the first six months of 2011. As a percent of net sales, sales and marketing expense was 42.2% and 42.4% in the first six months of 2012 and 2011, respectively.

Table of Contents

General and Administrative Expense General and administrative expense decreased \$7.2 million, or 20.1%, in the first six months of 2012 to \$28.9 million compared to \$36.1 million in the first six months of 2011. General and administrative expense as a percent of net sales was 12.3% in the first six months of 2012 compared to 15.7% 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 \$1.1 million and \$6.6 million of expenses in the first six months of 2012 and 2011, respectively related to regenerative stimulation and Mexico FCPA investigations. During the first six months of 2011, we incurred \$3.2 million of senior management succession charges.

Research and Development Expense Research and development expense increased \$4.6 million in the first six months of 2012 to \$16.3 million compared to \$11.7 million for the same period last year. As a percent of sales, research and development expense was 6.9% in the first six months of 2012 compared to 5.1% for the same period last year. The increase in research and development expenses in the first six months of 2012 compared to the same period in the prior year was due to a \$3.1 million charge or 1.3% of net sales for an arbitration resolution related to a 2008 co-development agreement and a \$1 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 \$1.1 million in the first six months of 2012 and 2011.

Charges Related to U.S. Government Resolutions The Company recorded a charge of \$1.4 million in the first six months of 2012 which represents imputed interest accrued from the respective settlement in principle dates in 2011 and 2012 through June 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 six 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 six 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 Promeca subsidiary.

Interest Expense, net Interest expense, net was \$3.5 million for the first six months of 2012 compared to \$4.6 million for the same period last year, primarily as the result of a lower rate of effective interest and a lower year over year outstanding debt balance repaid with a portion of the proceeds from the sale of Breg, Inc.

Other Income and Expense Other income (expense) was de minimis and \$1.5 million for the first six 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 33.8% and (85.1%) during the first six months of 2012 and 2011, respectively. The principal factors affecting our effective tax rate for the first six 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 six 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 six months of 2011, we did not record a tax benefit associated with the expense attributable to the charges related to U.S.

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

Government resolutions due to the uncertainty of the extent to which these expenses would be deductible for income tax purposes at that time. The effective tax rate for the first six months of 2012 and 2011 was 37.0% and 37.9%, respectively, excluding the impact of the discrete charges.

Discontinued operations Discontinued operations in the first six months of 2012 and 2011 includes the results of our Sports Medicine GBU up to May 24, 2012 (the closing date of the sale of Breg), net of income taxes. The first six months of 2012 also include the gain on the sale of Breg, of \$1.3 million, net of income taxes of \$0.2 million.

Net Income Net income for the first six months of 2012 was \$23.2 million, or \$1.24 per basic and \$1.21 per diluted share, compared to net loss of \$25.8 million, or \$(1.43) 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 June 30, 2012 were \$123 million, of which \$72.9 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 \$57.8 million and \$23.4 million for the six months ended June 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 \$49.0 million to net income of \$23.2 million for the six months ended June 30, 2012 from a net loss of \$25.8 million for the comparable period in the prior year. Non-cash items for the six months ended June 30, 2012 decreased \$7.7 million to \$11.6 million compared to non-cash items of \$19.3 million in the same period of 2011. Working capital accounts consumed \$21.6 million and \$16 million of cash for the six months ended June 30, 2012 and 2011, respectively. For the six months ended June 30, 2012, working capital accounts were impacted by \$41.5 million in cash received by the Company from the Blackstone escrow fund which was recorded in Restricted Cash in accordance with the credit facility. A \$32 million portion of this amount is earmarked for payment of the Blackstone settlement.

For the six months ended June 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 114 days at June 30, 2012 and 99 days at June 30, 2011 excluding our former sports medicine global business unit, and inventory turns of 1.2 times as of June 30, 2012 and 1.1 times as of June 30, 2011. The increase in DSO during the period was partially related to the additional working capital investment made associated with our MTF partnership as well as temporary delays in billing capabilities experienced in the first quarter of 2012 related to a system conversion and office relocation in two of our foreign jurisdictions.

Net cash provided by investing activities was \$140.1 million for the six months ended June 30, 2012 compared to net cash used in investing activities of \$16.5 million for the six months ended June 30, 2011. During the second quarter of 2012 we sold Breg, Inc. for net proceeds of \$153.1 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 six months ended June 30, 2012 and 2011, we invested \$13.0 million and \$11.3 million in capital expenditures, respectively.

Net cash used in financing activities was \$180.9 million for the six months ended June 30, 2012 compared to net cash provided by financing activities of \$6.7 million for the six months ended June 30, 2011. During the six months ended June 30, 2012, we repaid approximately \$168.7 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 \$2.5 million during the six months ended June 30, 2011. Our restricted cash balance usage increased \$23.5 million to \$25.8 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 six months ended June 30, 2012 and 2011, we received proceeds of \$13.3 million and \$13.5 million, respectively, from the issuance of 481,037 shares and 515,318 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

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

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 (see Note 15) 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. In June 2012 we paid down an additional \$20 million of amounts outstanding under the Revolving Credit Facility.

Table of Contents

As of June 30, 2012, the Term Loan Facility had been repaid in full and there was \$40 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 June 30, 2012, the entire Revolving Credit Facility was at the LIBOR rate plus a margin of 3.00%. 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 June 30, 2012 was 3.3% 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 16 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. We expect to be in compliance with our covenants prospectively.

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 June 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 June 30, 2012 and December 31, 2011 was \$200 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 June 30, 2012 and December 31, 2011 was \$72.9 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 June 30, 2012 and December 31, 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were \$2.1 million and \$3.5 million,

respectively.

At June 30, 2012, we had outstanding borrowings of 0.4 million (\$0.5 million) and unused available line of credit of approximately 6.9 million (\$8.7 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 \$160 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 near term.

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 June 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 June 30, 2012, \$40 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 June 30, 2012, our effective interest rate on our Credit Facilities was 3.3%. Based on the balance outstanding under the Credit Facilities as of June 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 June 30, 2012, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million (\$29.3 million). We recorded an unrealized foreign currency loss during the six months ended June 30, 2012 of \$0.7 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 six months ended June 30, 2012, we recorded a foreign currency gain of \$0.4 million 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 June 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

We are party to outstanding legal proceedings, investigations and claims as described below. We believe that it is unlikely that the outcome of each of these matters, including the matters discussed below, will have a material adverse effect on our Company and its subsidiaries as a whole, notwithstanding that the unfavorable resolution of any matter may have a material effect on our net earnings (if any) in any particular quarter. However, we cannot predict with any certainty the final outcome of any legal proceedings, investigations (including any settlement discussions with the government seeking to resolve such investigations) or claims made against us as described in the paragraphs below, and there can be no assurance that the ultimate resolution of any such matter will not have a material adverse impact on our consolidated financial position, results of operations, or cash flows.

We record accruals for certain 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. We evaluate, 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, we do 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 we disclose a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If we 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 we consider 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, our experience in similar matters and the experience of other companies, the facts available to us at the time of assessment, and how we intend to respond, or have responded, to the proceeding, investigation or claim. Our assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where we are 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 we believe a reasonable estimate of loss, or range of loss, can be made. In such instances, we believe 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 described in the paragraphs below, in the normal course of our business, we are 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, we accrue appropriate amounts in the accompanying financial statements and provide disclosures as to the possible range of loss in excess of the amount accrued, if such range is reasonably estimable. We believe losses are individually and collectively immaterial as to a possible loss and range of loss.

Litigation

Matters Related To Blackstone Medical, Inc. and Related Escrow Claims

On or about July 23, 2007, our subsidiary, Blackstone Medical, Inc. (Blackstone) received a subpoena issued by the Office of Inspector General of the Department of Health and Human Services (HHS-OIG), under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena sought documents for the period January 1, 2000 through July 31, 2006, which is prior to Blackstone s acquisition by us. We believe that the subpoena concerned the compensation of physician consultants and related matters. On September 17, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between us, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the Blackstone Merger Agreement), for any losses to us resulting from this matter. We were subsequently notified by legal counsel for the former shareholders of Blackstone that the representative of the former shareholders of Blackstone objected to the indemnification claim and intended to contest it in accordance with the terms of the Blackstone Merger Agreement.

Table of Contents

On or about January 7, 2008, we received a federal grand jury subpoena from the U.S. Attorney's Office for the District of Massachusetts (Boston USAO). The subpoena sought documents from us for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerned the compensation of physician consultants and related matters, and further believe that it was associated with HHS-OIG's investigation of such matters. On September 18, 2008, we submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. On or about April 29, 2009, counsel received a HIPAA subpoena issued by the U.S. Department of Justice (DOJ). The subpoena sought documents from us for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerned the compensation of physician consultants and related matters, and further believe that it was associated with HHS-OIG's investigation of such matters, as well as the January 7, 2008 federal grand jury subpoena. On or about August 26, 2010, counsel for Orthofix Inc. and Blackstone executed a tolling agreement with the Boston USAO (the Tolling Agreement) that extended an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate to include the period from December 1, 2008 through and including October 31, 2010. On or about February 1, 2011, the parties further extended the tolling of the statute of limitations through and including May 31, 2011 with respect to any criminal proceedings that the government might later initiate.

On or about December 5, 2008, we obtained a copy of a qui tam complaint filed by Susan Hutcheson and Philip Brown against us and Blackstone in the U.S. District Court for the District of Massachusetts. A qui tam action is a civil lawsuit brought by an individual for an alleged violation of a federal statute, in which DOJ has the right to intervene and take over the prosecution of the lawsuit at its option. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of DOJ and prior to the unsealing of the complaint (which was unsealed by the court on or about November 24, 2008), we submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. On November 21, 2008, the U.S. Department of Justice filed a notice of non-intervention in the case. The complaint was served on Blackstone on or about March 24, 2009. Counsel for the plaintiffs filed an amended complaint on June 4, 2009. The amended complaint sets forth a cause of action against Blackstone under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants; Orthofix is not named as a defendant in the amended complaint. We understand that this lawsuit was related to the matters described above involving HHS-OIG, the Boston USAO, and DOJ. On or about March 12, 2010, the United States District Court for the District of Massachusetts granted Blackstone's motion to dismiss and, on March 15, 2010, entered judgment in favor of Blackstone. On June 1, 2011, the United States Court of Appeals for the First Circuit reversed the motion to dismiss and remanded to the district court for further proceedings. In response to a joint motion to stay the action, on August 22, 2011, the United States District Court for the District of Massachusetts entered an order administratively closing the lawsuit for a period of no more than ninety (90) days. On August 30, 2011, Blackstone filed with the United States Supreme Court a Petition for a Writ of Certiorari to review the June 1, 2011 judgment of the United States Court of Appeals for the First Circuit, which was denied on December 5, 2011.

In January 2012, after a series of ongoing discussions and negotiations with the Boston USAO, our board of directors approved an agreement in principle to pay \$32 million to resolve the matters described in the immediately preceding paragraphs. We are currently in discussions with the Boston USAO, DOJ, and HHS-OIG, as to the terms of definitive written agreements to finally resolve these matters. As part of the resolution of this matter (and matters described below related to our regenerative stimulation business), on June 6, 2012, Orthofix International N.V., Orthofix Inc. and Blackstone Medical, Inc. entered into a five-year Corporate Integrity Agreement with HHS-OIG. (The Corporate Integrity Agreement is further described below under the subheading Corporate Integrity Agreement with HHS-OIG .) Based on information currently available, we believe that it is probable that a final written definitive settlement agreement with the U.S. Government will be entered into on these economic terms, which, as described below, would be fully funded from the escrow fund established in connection with the Blackstone Merger Agreement. There can be no assurance that we will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, we believe that the likelihood of any such additional material loss in excess of this amount is remote.

In 2007 and 2008, we received certain other subpoenas from state and federal entities related to Blackstone's financial relationship with physicians, which we have described in prior reports. We have fully responded to each of these subpoenas, and there are currently no pending proceedings related to any of these matters.

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

Under the Blackstone Merger Agreement, the former shareholders of Blackstone agreed to indemnify us for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders were limited to a cumulative aggregate amount of \$66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was \$50.0 million. As of December 31, 2011, the escrow fund contained \$47.5 million.

Table of Contents

In February 2012, we reached an agreement with the representative of the former shareholders of Blackstone resolving all outstanding escrow and indemnification claims under the Blackstone Merger Agreement. Under this agreement, approximately \$42.5 million was distributed to us from the escrow fund (which will be used, among other things, to fund the proposed \$32 million settlement in principle described above). Each of the Company and the former shareholders of Blackstone also mutually released each other from all further claims against each other related to these matters. As of September 30, 2011, we had recognized \$15.5 million as an escrow receivable on our consolidated balance sheet, reflecting previously incurred expenses that we believed were reasonably assured of collection. We received approximately \$9.5 million in cash from the escrow fund after application of (i) the \$32 million allocated to the settlement in principle described above with the government and (ii) approximately \$1 million of other fees incurred with respect to this matter since September 30, 2011. As a result, we recorded a charge of approximately \$6 million during the fourth quarter of 2011 for previously incurred legal fees that were reflected in this escrow receivable balance as of September 30, 2011. The Company recorded a charge of \$0.2 million in the second quarter of 2012 which represents imputed interest on the settlement accrued through June 30, 2012.

Matters Related to Regenerative Stimulation Business

On or about April 10, 2009, we received a HIPAA subpoena (HIPAA subpoena) issued by the Boston USAO. The subpoena sought documents concerning, among other things, our promotion and marketing of our regenerative stimulator devices (which we have also described in the past as our bone growth stimulator devices). The Boston USAO issued several subsequent document and testimony subpoenas. We cooperated with these requests.

On or about April 14, 2009, we obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the U.S. District Court for the District of Massachusetts against the us, Orthofix Inc. and other companies that have allegedly manufactured regenerative stimulation devices, including Orthologic Corp., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. The complaint, as subsequently amended in 2010, alleged various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of regenerative stimulation devices. The complaint also included claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-Kickback Act by providing free products to physicians, waiving patients insurance co-payments and providing inducements to independent sales agents to generate business.

On April 28, 2011, after a series of ongoing discussions and negotiations with the Boston USAO, our board of directors approved an agreement in principle proposed by the Boston USAO to resolve the criminal and civil matters described in the immediately preceding two paragraphs. On June 6, 2012, we 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 Mr. Bierman. This settlement agreement finally resolves these matters.

In connection with the settlement agreement, our wholly-owned subsidiary, Orthofix Inc., entered into a plea agreement with the Boston USAO and DOJ on June 7, 2012 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.

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

We have agreed to pay \$34.2 (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, we agreed in July 2012 to pay Mr. Bierman's counsel \$1.0 million in fees. We previously recorded a charge of \$43 million during the first quarter of 2011 in anticipation of the settlement. The Company recorded a charge of \$1.2 million in the second quarter of 2012 which represents imputed interest on the settlement accrued through June 30, 2012.

The settlement is neither an admission of liability by the Company or its subsidiaries nor a concession by the United States or the civil qui tam relator that their claims are not well founded, except as to such admissions as Orthofix Inc. makes in connection with its guilty plea under the Plea Agreement.

Corporate Integrity Agreement with HHS-OIG

On June 6, 2012, in connection with our settlement of the matters described above related to our regenerative stimulation business, and in anticipation of a final settlement of the government investigation and related qui tam complaint described above related to Blackstone Medical, Inc., we also entered into a five-year corporate integrity agreement with HHS-OIG (the "CIA"). The CIA acknowledges the existence of our current compliance program, and requires that we continue to maintain during the term of the CIA a compliance program designed to promote compliance with federal healthcare and Food and Drug Administration (FDA) requirements. We are also required to maintain several elements of the existing program during the term of the CIA, including maintaining a Chief Compliance Officer, a Compliance Committee, and a Code of Conduct. The CIA requires that we conduct certain additional compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations.

Table of Contents

Pursuant to the CIA, we are required to notify the HHS-OIG in writing, among other things, of: (i) any ongoing government investigation or legal proceeding involving an allegation that the Company has committed a crime or has engaged in fraudulent activities; (ii) any other matter that a reasonable person would consider a probable violation of applicable criminal, civil, or administrative laws related to compliance with Federal healthcare programs or FDA requirements; and (iii) any change in location, sale, closing, purchase, or establishment of a new business unit or location related to items or services that may be reimbursed by Federal healthcare programs. We are also subject to periodic reporting and certification requirements attesting that the provisions of the CIA are being implemented and followed, as well as certain document and record retention mandates. The CIA provides that in the event of an uncured material breach of the CIA, we could be excluded from participation in Federal healthcare programs and/or subject to monetary penalties.

Matters Related to Promeca

During the second quarter of 2010 internal management review of Promeca S.A. de C.V. (Promeca), one of our Mexican subsidiaries, we received allegations of improper payments by certain of Promeca's local employees in Mexico to employees of a Mexican governmental healthcare entity. We engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation (the Promeca Internal Investigation) focusing on compliance with the Foreign Corrupt Practices Act (FCPA) and voluntarily contacted the Securities and Exchange Commission (the SEC) and DOJ to advise both agencies that an internal investigation was underway. Promeca accounted for approximately one percent of our consolidated net sales and consolidated total assets.

We completed the Promeca Internal Investigation in April 2011 and commenced settlement discussions with the U.S. Government regarding this matter in May 2011. In January 2012, we reached an agreement in principle to settle these matters with DOJ, and on July 10, 2012, we entered into definitive agreements with DOJ and the SEC agreeing to settle this matter. As part of the settlement, we have entered into (i) a consent to final judgment (the SEC Consent) with the SEC in a civil matter filed by the SEC on the same date in the U.S. District Court for the Eastern District of Texas and (ii) a deferred prosecution agreement (the DPA) with DOJ. These agreements remain subject to review and approval by the U.S. District Court for the Eastern District of Texas, and there can be no assurance that they will be approved by the court on the terms proposed.

Under the terms of the SEC Consent, we will settle 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. We have also agreed to pay a fine of \$2.2 million to the U.S. Government pursuant to the terms of the DPA. We 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 DOJ and the SEC. We made payment of the amounts owed pursuant to the DPA in July 2012, and expect to make payments pursuant to the SEC Consent in the third fiscal quarter of 2012.

As part of the DPA, which has a term of 3 years, DOJ has agreed not to pursue any criminal charges against us in connection with this matter if we comply with the terms of the DPA. The DPA takes note of our self-reporting of this matter to DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by us. The DPA provides that we shall continue to cooperate fully with DOJ in any future matters related to corrupt payments, false books and records or inadequate internal controls. In that regard, we have represented that we have implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws. We will periodically report to DOJ during the term of the DPA regarding such remediation and implementation of compliance measures.

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

In addition, under the terms of the SEC Consent, we will periodically report to the SEC during a 2-year term regarding the status of such remediation and implementation of compliance measures. The SEC Consent and the DPA do not provide for the appointment of any independent external monitor by DOJ or the SEC.

Matters Related to Our Former Breg Subsidiary and Possible Indemnification Obligations

On May 24, 2012, we 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, and has recorded the related charge to discontinued operations, including the product liability cases with respect to such products described above. We have established an accrual of \$2.0 million for its indemnification obligations in connection with the July 2012 verdict described in the preceding paragraph, however, actual liability in this case could be higher or lower than the amount accrued. We have 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.

Our former subsidiary, Breg, Inc ("Breg"), which we divested in May 2012, was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008. Since 2008, numerous product liability cases have been filed in the United States alleging that the local anesthetic, when dispensed by such infusion pumps inside a joint, causes a rare arthritic condition called chondrolysis. We believe that meritorious defenses exist to these claims and Breg is vigorously defending these cases. One of our insurance carriers has asserted to us that certain potential losses related to this matter are not covered by our insurance coverage, and we are currently in arbitration with this carrier.

On or about August 2, 2010, Breg received a HIPAA subpoena issued by the DOJ. The subpoena seeks documents from us and our subsidiaries for the period of January 1, 2000 through the date of the subpoena. We believe that document production in response to the subpoena is completed as of July 2012. We believe that this subpoena relates to an investigation by the DOJ into whether Breg's sale, marketing and labeling of local infusion pumps for pain management, prior to Breg's divestiture of this product line in 2008, complied with FDA regulations and federal law. On January 27, 2012, we were orally notified by a U.S. Government official that a civil investigation of Breg was pending in connection with this matter. We are currently cooperating with the U.S. Government in connection with this matter.

Table of Contents

At the time of its divestiture by us, Breg was currently and had been engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases have been filed in recent years, mostly in California state court, alleging that the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units. The majority of these cases are at an early stage and no conclusion can be drawn at the present time regarding their potential outcome. However, we believe that meritorious defenses exist to these claims. In July 2012, a jury in one case returned a verdict providing for approximately \$2.0 million in compensatory damages to the plaintiff against Breg, and could assess additional exemplary damages in the future. We expect the \$2.0 million compensatory award to be covered by existing insurance policies, while any exemplary portion of an award will not be covered by insurance. The case remains subject to further post-verdict motions and appeals.

Item 1A. Risk Factors

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

If we fail to comply with the terms of our Deferred Prosecution Agreement and Corporate Integrity Agreement, we may be subject to criminal prosecution and/or exclusion from federal healthcare programs.

On June 6, 2012, in connection with our settlement of a U.S. government investigation and related qui tam complaint related to our regenerative stimulation business, and in anticipation of a final settlement of the U.S. government investigation and related qui tam complaint related to Blackstone Medical, Inc., we entered into a five-year corporate integrity agreement (the "CIA") with the Office of Inspector General of the Department of Health and Human Services ("HHS-OIG"). The CIA acknowledges the existence of our current compliance program, and requires that we continue to maintain during the term of the CIA a compliance program designed to promote compliance with federal healthcare and Food and Drug Administration ("FDA") requirements. We are also required to maintain several elements of the existing program during the term of the CIA, including maintaining a Chief Compliance Officer, a Compliance Committee, and a Code of Conduct. The CIA requires that we conduct certain additional compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations. Pursuant to the CIA, we are required to notify the HHS-OIG in writing, among other things, of: (i) any ongoing government investigation or legal proceeding involving an allegation that the Company has committed a crime or has engaged in fraudulent activities; (ii) any other matter that a reasonable person would consider a probable violation of applicable criminal, civil, or administrative laws related to compliance with Federal healthcare programs or FDA requirements; and (iii) any change in location, sale, closing, purchase, or establishment of a new business unit or location related to items or services that may be reimbursed by Federal healthcare programs. We are also subject to periodic reporting and certification requirements attesting that the provisions of the CIA are being implemented and followed, as well as certain document and record retention mandates. The CIA provides that in the event of an uncured material breach of the CIA, we could be excluded from participation in Federal healthcare programs and/or subject to prosecution and subject to other monetary penalties, each of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

On July 10, 2012, we entered into definitive agreements with the U.S. Department of Justice ("DOJ") and Securities and Exchange Commission (the "SEC") agreeing to settle our self-initiated and self-reported internal investigation of our Mexican subsidiary, Promeca S.A. de C.V. ("Promeca"), regarding non-compliance by Promeca with the Foreign Corrupt Practices Act (the "FCPA"). As part of the settlement, we entered into a 3-year deferred prosecution agreement with DOJ. DOJ has agreed not to pursue any criminal charges against us in connection with this matter if we comply with the terms of the DPA. The DPA takes note of our self-reporting of this matter to DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by us. The DPA provides that we shall continue to cooperate fully with DOJ in any future matters related to corrupt payments, false books and records or inadequate internal controls. In that regard, we have represented that we have implemented and will continue to implement a compliance and ethics program designed to

prevent and detect violations of the FCPA and other applicable anti-corruption laws. We will periodically report to DOJ during the term of the DPA regarding such remediation and implementation of compliance measures. As part of the settlement, we also agreed to certain reporting obligations to the SEC regarding the status of our remediation and implementation of compliance measures. In the event that we fail to comply with these obligations, we could be subject to criminal prosecution by DOJ for the FCPA-related matters we self-reported. Such a criminal prosecution could subject us to penalties that could have a material adverse effect our business, financial condition, results of operations and cash flows.

Table of Contents

Our recently announced settlements with the U.S. government remain subject to U.S. federal court review and approval, and there can be no assurance that such approval will be obtained.

As described above, and as further described under the subheadings "Matters Related to Regenerative Stimulation Business" and "Matters Related to Promeca" in the Legal Proceedings section under Part II, Item 1 of this Quarterly Report on Form 10-Q, we have recently announced settlements in connection with (i) a U.S. government investigation and related qui tam complaint related to our regenerative stimulation business and (ii) a self-initiated and self-reported internal investigation of our Mexican subsidiary, Promeca, into allegations of non-compliance by Promeca with the FCPA. These settlements remain subject to review and approval, respectively, by the U.S. District Court for the District of Massachusetts and the U.S. District Court for the Eastern District of Texas. However, there can be no assurance that these agreements will be approved by the respective courts on the terms proposed. In the event that these agreements are not approved by the court, we could be required to further negotiate these agreements on terms different than those currently agreed. If these terms were to incur substantial additional monetary penalties, or additional material restrictions on our business, it could have a material adverse effect our business, financial condition, results of operations and cash flows.

We could be subject to indemnification obligations under our agreement with the purchaser of our former sports medicine business unit.

In May 2012, we sold our former sports medicine business unit, Breg, Inc., to an affiliate of Water Street Healthcare Partners II, L.P. pursuant to a stock purchase agreement between us and the buyer. Under the stock purchase agreement, we have agreed to indemnify the buyer with respect to certain specified matters, including (i) an ongoing U.S. government investigation and certain ongoing product liability matters relating to a previously owned infusion pump product line, and (ii) product liability claims relating to pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. These matters are further described under the subheading "Matters Related to Our Former Breg Subsidiary and Possible Indemnification Obligations" in the Legal Proceedings section under Part II, Item 1 of this Quarterly Report on Form 10-Q. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with these indemnified matters. In the event that they are substantial, it could have a material adverse effect our business, financial condition, results of operations and cash flows.

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

Table of Contents

Item 6. Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of August 4, 2006, among Orthofix International N.V., Orthofix Holdings, Inc., New Era Medical Limited, Blackstone Medical, Inc. and William G. Lyons, III, as Equityholders Representative (filed as an exhibit to the Company's current report on Form 8-K filed August 7, 2006 and incorporated herein by reference).
2.2	Asset Purchase Agreement, dated as of March 8, 2010, by and between Tyco Healthcare Group LP d/b/a Covidien, Covidien AG, Mallinckrodt do Brasil Ltda, Kendall de Mexico S.A. de C.V., Novamedix Limited, Novamedix Distribution Limited, Novamedix Services Limited, Promeca S.A. de C.V., Orthofix do Brasil, Orthofix S.r.l., Orthofix S.A., IntaventOrthofix Limited, Breg Mexico S. de R.I. de CV, and Implantes y Sistemas Medicos, Inc. (filed as an exhibit to the Company's current report on Form 8-K filed March 9, 2010 and incorporated herein by reference).
2.3	Stock Purchase Agreement, dated as of April 23, 2012, by and among Breg, Inc., Orthofix Holdings, Inc. and Breg Acquisition Corp. (filed as an exhibit to the Company's current report on Form 8-K filed April 24, 2012 and incorporated herein by reference).
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
3.2	Articles of Association of the Company as amended (filed as an exhibit to the Company's Annual report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.1	Credit Agreement, dated as of August 30, 2010, among Orthofix Holdings, Inc., Orthofix International N.V. and certain domestic subsidiaries of Orthofix International N.V., the several banks and other financial institutions as may from time to time become parties thereunder, and JPMorgan Chase, N.A. (filed as an exhibit to the Company's current report on Form 8-K filed August 31, 2010 and incorporated herein by reference).
10.2	First Amendment to Credit Agreement, dated May 4, 2011, among Orthofix Holdings, Inc., a Delaware corporation, Orthofix International N.V. (Orthofix International), a Netherlands Antilles corporation, certain domestic direct and indirect subsidiaries of Orthofix International, JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lender parties thereto (filed as an exhibit to the Company's current report on Form 8-K filed May 5, 2011 and incorporated herein by reference).
10.3+	Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
10.4	Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.5+	Amendment No. 2 to Matrix Commercialization Collaboration Agreement, dated as of January 9, 2012, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to amendment no. 1 to the Company's annual report on Form 10-K/A for the fiscal year ended December 31, 2011, filed May 1, 2012, and incorporated herein by reference).
10.6	Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
10.7*	Orthofix International N.V. 2012 Long-Term Incentive Plan.
10.8	Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference).

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

10.9 Orthofix International N.V. Staff Share Option Plan, as amended through April 22, 2003 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007 and incorporated herein by reference).

Table of Contents

- 10.10 Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company's current report on Form 8-K filed January 7, 2011).
- 10.11* Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (June 2012 grant).
- 10.12 Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.13 Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.14 Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2008) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
- 10.15 Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2008) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
- 10.16 Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2008) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
- 10.17 Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (post-2008) (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
- 10.18 Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
- 10.19 Inducement Grant Nonqualified Stock Option Agreement between Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the current report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
- 10.20 Inducement Grant Nonqualified Stock Option Agreement, dated April 1, 2011, between Orthofix International N.V. and Vicente Trelles (filed as an exhibit to the current report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).

Table of Contents

- 10.21 Second Amended and Restated Performance Accelerated Stock Options Agreement between Orthofix International N.V. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed October 15, 2008 and incorporated herein by reference).
- 10.22 Nonqualified Stock Option Agreement between Orthofix International N.V. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed October 15, 2008 and incorporated herein by reference).
- 10.23 Form of Award Letter Regarding Special Retention Cash Bonus Award (filed as an exhibit to the Company's current report on Form 8-K/A filed on February 23, 2011 and incorporated herein by reference).
- 10.24* Description of Director Compensation Policy
- 10.25 Form of Indemnity Agreement (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2008 and incorporated herein by reference).
- 10.26 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.27 Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.28 Letter Agreement, dated June 15, 2011, between Orthofix Inc., Orthofix International N.V. and Alan W. Milinazzo (filed as an exhibit to the Company's quarterly report on current report on Form 8-K filed June 16, 2011 and incorporated herein by reference).
- 10.29 Amended and Restated Employment Agreement, entered into and effective as of July 28, 2010, 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 3, 2010 and incorporated herein by reference).
- 10.30 Addendum to Amended and Restated Employment Agreement, entered into as of March 9, 2011, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's quarterly report on current report on Form 8-K filed March 15, 2011 and incorporated herein by reference).
- 10.31 Amended and Restated Employment Agreement, dated as of June 15, 2011 and effective as of August 1, 2011, by and between Orthofix Inc., Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the Company's quarterly report on current report on Form 8-K filed June 16, 2011 and incorporated herein by reference).
- 10.32 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).

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

Table of Contents

- 10.33 Amendment No. 1 to Amended and Restated Employment Agreement, dated August 4, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.34 Amendment No. 2 to Amended and Restated Employment Agreement, dated as of October 1, 2011, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed October 4, 2011 and incorporated herein by reference).
- 10.35 Employment Agreement, entered into on December 9, 2010, by and between Orthofix Inc. and Jeffrey M. Schumm (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
- 10.36 Employment Agreement, entered into as of March 2, 2011, by and between Orthofix Inc. and Brian McCollum (filed as an exhibit to the Company's quarterly report on current report on Form 8-K filed March 7, 2011 and incorporated herein by reference).
- 10.37 Employment Agreement, entered into as of April 1, 2011, by and between Orthofix Inc. and Vicente Trelles (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
- 10.38 Employment Agreement, entered into as of October 1, 2011, by and between Orthofix Inc. and Bryan McMillan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2011 and incorporated herein by reference).
- 10.39 Amended and Restated Employment Agreement, entered into on July 28, 2010, by and between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company's current report on Form 8-K filed August 3, 2010 and incorporated herein by reference).
- 10.40 Separation Letter Agreement, dated February 7, 2011, between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company's current report on Form 8-K filed on February 10, 2011 and incorporated herein by reference).
- 10.41 Amended and Restated Employment Agreement, entered into on July 1, 2009, by and between Orthofix Inc. and Eric Brown (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
- 10.42 Separation Letter Agreement, dated January 10, 2011, between Orthofix Inc. and Eric Brown (filed as an exhibit to the Company's current report on Form 8-K filed January 14, 2011 and incorporated herein by reference).
- 10.43 Form of Amendment to Stock Option Agreements (for Alan W. Milinazzo, Robert S. Vaters, Bradley R. Mason, Michael M. Finegan and Michael Simpson) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.44 Settlement Agreement, entered into on June 6, 2012, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, 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, Orthofix International N.V. and relator Jeffrey J. Bierman (filed as an exhibit to the Company's current report on Form 8-K/A filed June 7, 2012 and incorporated herein by reference).
- 10.45 Plea Agreement, entered into on June 7, 2012, among the United States Attorney for the District of Massachusetts, the Department of Justice and Orthofix Inc. (filed as an exhibit to the Company's current report on Form 8-K/A filed June 7, 2012 and incorporated herein by reference).
- 10.46 Corporate Integrity Agreement, entered into on June 6, 2012, between the Office of Inspector General of the Department of Health and Human Services and Orthofix International N.V. (filed as an exhibit to the Company's current report on Form 8-K/A filed June 7, 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.

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

- 32.1* Section 1350 Certification of Chief Executive Officer.
- 32.2* Section 1350 Certification of Chief Financial Officer.
- 101* The following materials from the Orthofix International N.V. Quarterly Report on Form 10-Q for the quarter ended June 30, 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: July 30, 2012

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

Date: July 30, 2012

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