ORTHOFIX INTERNATIONAL N V
Form 10-Q
May 04, 2012
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

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# FORM 10-Q

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**(Mark one)**

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

**For the quarterly period ended March 31, 2012**

**OR**

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

**For the transition period from to .**

**Commission File Number: 0-19961**

# ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

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

**599-9-4658525**

(Registrant s telephone number, including area code)

**Not applicable**

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

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

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

Large Accelerated filer x Accelerated filer o

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

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

As of April 30, 2012, 18,729,790 shares of common stock were issued and outstanding.

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**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, potentia 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 matters relating to our regenerative stimulation and spinal implant businesses, and the possible violations of the FCPA by our former Mexican orthopedic distribution entity, as well as certain product liability claims against our sports medicine global business unit), ongoing

governmental investigations of our businesses which could result in civil or criminal liability or findings of violations of law (as further described in the *Legal Proceedings* section of this Form 10-Q), 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*.

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**PART I. FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements**

**ORTHOFIX INTERNATIONAL N.V.**

**Condensed Consolidated Balance Sheets**

| (U.S. Dollars, in thousands, except share data) | March 31, 2012 (unaudited) | December 31, 2011 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 47,053 | $ 33,207 |
| Restricted cash | 79,371 | 47,105 |
| Trade accounts receivable, less allowance for doubtful accounts of $11,913 and $10,045 at March 31, 2012 and December 31, 2011, respectively | 156,495 | 146,538 |
| Inventories, net | 90,939 | 91,247 |
| Deferred income taxes | 19,028 | 16,867 |
| Escrow receivable | | 41,537 |
| Prepaid expenses and other current assets | 21,889 | 28,089 |
| Total current assets | 414,775 | 404,590 |
| Property, plant and equipment, net | 53,634 | 52,124 |
| Patents and other intangible assets, net | 36,399 | 37,515 |
| Goodwill | 180,435 | 179,373 |
| Deferred income taxes | 9,958 | 9,662 |
| Other long-term assets | 12,385 | 12,287 |
| Total assets | $ 707,586 | $ 695,551 |
| **Liabilities and shareholders equity** | | |
| Current liabilities: | | |
| Bank borrowings | $ 1,423 | $ 1,318 |
| Current portion of long-term debt | 20,000 | 17,500 |
| Trade accounts payable | 17,401 | 20,105 |
| Accrued charges related to U.S. Government resolutions | 82,500 | 82,500 |
| Other current liabilities | 50,173 | 53,989 |
| Total current liabilities | 171,497 | 175,412 |
| Long-term debt | 184,945 | 191,195 |
| Deferred income taxes | 9,521 | 9,777 |
| Other long-term liabilities | 3,215 | 3,996 |
| Total liabilities | 369,178 | 380,380 |
| Contingencies (Note 15) | | |
| Shareholders equity: | | |
| Common shares $0.10 par value; 50,000,000 shares authorized; 18,728,157 and 18,465,444 issued and outstanding as of March 31, 2012 and December 31, 2011, respectively | 1,873 | 1,846 |

| | | | | |
|---|---|---|---|---|
| Additional paid-in capital | | 222,794 | | 214,310 |
| Retained earnings | | 109,270 | | 97,254 |
| Accumulated other comprehensive income | | 4,471 | | 1,761 |
| Total shareholders equity | | 338,408 | | 315,171 |
| Total liabilities and shareholders equity | $ | 707,586 | $ | 695,551 |

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

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**ORTHOFIX INTERNATIONAL N.V.**

**Condensed Consolidated Statements of Operations**

**For the three months ended March 31, 2012 and 2011**

| (Unaudited, U.S. Dollars, in thousands, except share and per share data) | Three Months Ended March 31, 2012 | 2011 |
|---|---|---|
| Net sales | $ 143,141 | $ 139,165 |
| Cost of sales | 32,882 | 33,361 |
| Gross profit | 110,259 | 105,804 |
| Operating expenses | | |
| Sales and marketing | 58,280 | 55,598 |
| General and administrative | 20,943 | 22,960 |
| Research and development | 7,745 | 6,052 |
| Amortization of intangible assets | 1,247 | 1,255 |
| Charges related to U.S. Government resolutions (Note 15) | | 46,000 |
| | 88,215 | 131,865 |
| Operating income | 22,044 | (26,061) |
| Other income (expense) | | |
| Interest expense, net | (2,225) | (2,416) |
| Other expense, net | (746) | (1,073) |
| | (2,971) | (3,489) |
| Income (loss) before income taxes | 19,073 | (29,550) |
| Income tax expense | (7,057) | (6,251) |
| Net income (loss) | $ 12,016 | $ (35,801) |
| Net income (loss) per common share: | | |
| Basic | $ 0.64 | $ (2.00) |
| Diluted | $ 0.63 | $ (2.00) |
| Weighted average number of common shares: | | |
| Basic | 18,675,694 | 17,937,280 |
| Diluted | 19,116,195 | 17,937,280 |
| Comprehensive income (loss) | $ 14,726 | $ (32,711) |

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

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**ORTHOFIX INTERNATIONAL N.V.**

**Condensed Consolidated Statements of Cash Flows**

**For the three months ended March 31, 2012 and 2011**

| (Unaudited, U.S. Dollars, in thousands) | Three Months Ended March 31, 2012 | 2011 |
|---|---|---|
| Cash flows from operating activities: | | |
| Net income (loss) | $ 12,016 | $ (35,801) |
| Adjustments to reconcile net income (loss) to net cash provided by operating activities: | | |
| Depreciation and amortization | 5,667 | 5,339 |
| Amortization of debt costs | 296 | 249 |
| Provision for doubtful accounts | 3,154 | 1,833 |
| Deferred income taxes | (828) | (856) |
| Share-based compensation | 1,480 | 1,509 |
| Provision for inventory obsolescence | 649 | 798 |
| Excess tax benefit on non-qualified stock options | (390) | (585) |
| Other | (2,221) | 1,379 |
| Change in operating assets and liabilities, net of effect of acquisitions: | | |
| Trade accounts receivable | (11,943) | 1,257 |
| Inventories | 732 | (7,958) |
| Escrow receivable | 41,537 | (288) |
| Prepaid expenses and other current assets | 6,317 | 2,007 |
| Trade accounts payable | (3,103) | 185 |
| Charges related to U.S. Government resolutions | | 46,000 |
| Other current liabilities | (4,397) | 3,711 |
| Net cash provided by operating activities | 48,966 | 18,779 |
| Cash flows from investing activities: | | |
| Capital expenditures for property, plant and equipment | (6,372) | (5,547) |
| Capital expenditures for intangible assets | (151) | (106) |
| Payment made in connection with acquisition | | (5,250) |
| Net cash used in investing activities | (6,523) | (10,903) |
| Cash flows from financing activities: | | |
| Net proceeds from issuance of common shares | 6,641 | 7,326 |
| Repayments of long-term debt | (3,750) | (1,250) |
| Proceeds from (repayment of) bank borrowings, net | 69 | (1,886) |
| Changes in restricted cash | (32,271) | (2,442) |
| Cash payment for purchase of minority interest in subsidiary | | (517) |
| Excess tax benefit on non-qualified stock options | 390 | 585 |
| Net cash (used in) provided by financing activities | (28,921) | 1,816 |
| Effect of exchange rate changes on cash | 324 | 134 |
| Net increase in cash and cash equivalents | 13,846 | 9,826 |
| Cash and cash equivalents at the beginning of the period | 33,207 | 13,561 |
| Cash and cash equivalents at the end of the period | $ 47,053 | $ 23,387 |

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

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**ORTHFIX INTERNATIONAL N.V.**

**Notes to the Unaudited Condensed Consolidated Financial Statements**

**1. 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 three reportable segments: Spine, Orthopedics, and Sports Medicine supported by Corporate activities.

**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 three months ended March 31, 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 in Note 3- Inventories and Note 4- Patents and other intangible assets 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 financial statements by providing an alternative to present the components of net income and comprehensive income as either one or two 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 of this ASU as of March 31, 2012 and it did not have a material impact on the Company s financial statements.

**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) | March 31, 2012 | December 31, 2011 |
|---|---|---|
| Raw materials | $ 12,341 | $ 13,192 |
| Work-in-process | 6,901 | 6,150 |
| Finished products | 53,679 | 53,526 |
| Field inventory | 38,798 | 39,401 |
| Consignment inventory | 8,565 | 8,418 |
| | 120,284 | 120,687 |
| Less reserve for obsolescence | (29,345) | (29,440) |
| | $ 90,939 | $ 91,247 |

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

**4. Patents and other intangible assets**

| (US$ in thousands) | March 31, 2012 | December 31, 2011 |
|---|---|---|
| **Cost** | | |
| Patents and developed technologies | $ 29,680 | $ 29,065 |
| Trademarks definite lived (subject to amortization) | 696 | 646 |
| Trademarks indefinite lived (not subject to amortization) | 23,057 | 23,057 |
| Contracts with insurers | 1,000 | 1,000 |
| Distribution networks | 43,586 | 43,586 |
| | 98,019 | 97,354 |
| **Accumulated amortization** | | |
| Patents and developed technologies | (22,840) | (21,811) |
| Trademarks definite lived (subject to amortization) | (450) | (416) |
| Contracts with insurers | (331) | (262) |
| Distribution networks | (37,999) | (37,350) |
| **Patents and other intangible assets, net** | $ 36,399 | $ 37,515 |

Amortization expense for intangible assets is estimated to be approximately $4.0 million for the remainder of 2012 and $4.4 million, $1.3 million, $1.2 million, $1.5 million and $0.9 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 | $ 179,373 |
| Acquisitions | |
| Foreign currency | 1,062 |
| At March 31, 2012 | $ 180,435 |

**6. Bank borrowings**

Borrowings under lines of credit consist of borrowings in Euros used to fund international operations. The borrowings under such facilities were $1.4 million and $1.3 million at March 31, 2012 and December 31, 2011, respectively. The weighted average interest rates on borrowings under lines of credit as of March 31, 2012 and December 31, 2011 were 6.47% and 4.02%, respectively.

The Company had an unused available line of credit of 6.2 million ($8.3 million) and 6.3 million ($8.1 million) at March 31, 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.

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

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

As of March 31, 2012 and December 31, 2011 the Company had $87.5 million and $91.3 million, respectively, 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 March 31, 2012 and 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%. 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 March 31, 2012 and December 31, 2011 was 3.4%.

The principal amount of the Term Loan Facility amortizes at the rate of 5%, 15%, 25%, 25% and 30% in year 1, 2, 3, 4 and 5, respectively. Amortization payments began on December 31, 2010 and end on December 31, 2015. Outstanding principal on the Revolving Credit Facility is due on December 31, 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 15). 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. Management believes the Company was in compliance with the affirmative and negative covenants at March 31, 2012 and there were no events of default.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company s Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company.

Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of March 31, 2012 and December 31, 2011 was $187.2 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 March 31, 2012 and December 31, 2011 was $79.4 million and $47.1 million, respectively.

In conjunction with obtaining the Credit Facilities and the Credit Agreement, as amended, the Company incurred debt issuance costs of $5.0 million. These costs are being amortized using the effective interest method over the life of the Credit Facilities. As of March 31, 2012 and December 31, 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were $3.2 million and $3.5 million, respectively.

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

**8. Derivative instruments**

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

| (US$ in thousands) As of March 31, 2012 | Fair value: favorable (unfavorable) | Balance sheet location |
|---|---|---|
| Cross-currency swap | $ (13) | Other long-term liabilities |
| **As of December 31, 2011** | | |
| Cross-currency swap | $ 1,011 | Other long-term assets |

| (US$ in thousands) | Three Months Ended March 31, 2012 | 2011 |
|---|---|---|
| Cross-currency swap unrealized gain recorded in other comprehensive income (loss), net of taxes | $ 509 | $ 1,102 |

*Cross-currency swap*

In 2006, the Company entered into a cross-currency swap agreement with Wells Fargo to manage its cash flows related to foreign currency exposure for a portion of the Company s intercompany receivable of a U.S. dollar functional currency subsidiary that is denominated in Euro. The derivative instrument, a ten-year fully amortizable agreement with an initial notional amount of $63.0 million, was scheduled to expire on December 30, 2016. Upon executing the Company s Credit Agreement (See Note 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).

**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 March 31, 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, and therefore, the carrying value is considered to approximate the fair value.

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

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 March 31, 2012 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Derivative financial instruments (1) | | | | |
| Cash flow hedges | | | | |
| Cross-currency hedge | $ (13) | $ | $ (13) | $ |

(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 | $ |

**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 $297 | | 509 | 509 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Foreign currency translation adjustment (1) | | 2,201 | | | | 2,201 |
| Balance at March 31, 2012 | $ | 4,094 | $ | 377 | $ | 4,471 |

(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:

| | Three Months Ended March 31, | |
|---|---|---|
| **(US$ in thousands)** | **2012** | **2011** |
| Net income (loss) | $ 12,016 | $ (35,801) |
| Other comprehensive income (loss): | | |
| Unrealized gain on cross-currency swap, net of tax | 509 | 1,102 |
| Foreign currency translation adjustment | 2,201 | 1,988 |
| Total comprehensive income (loss) | $ 14,726 | $ (32,711) |

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

## 11. Earnings per share

For the three months ended March 31, 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 March 31, | |
|---|---|---|
| | **2012** | **2011** |
| Weighted average common shares-basic | 18,675,694 | 17,937,280 |
| Effect of dilutive securities: | | |
| Unexercised stock options net of treasury share repurchase | 440,501 | |
| Weighted average common shares-diluted | 19,116,195 | 17,937,280 |

No adjustment has been made in the three months ended March 31, 2011 for any common stock equivalents because their effects would be anti-dilutive. For the three months ended March 31, 2011, potentially dilutive shares totaled 211,196.

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 714,686 and 1,783,844 outstanding options not included in the diluted earnings per share computation for the three months ended March 31, 2012 and 2011, respectively, because the inclusion of these options was anti-dilutive.

## 12. Share-based compensation

All share-based compensation costs are measured at the grant date, based on the estimated fair value of the award, and are recognized as expense in the condensed consolidated statements of operations over the requisite service period. Commencing in June 2007, the Company offered restricted shares in addition to stock options as a form of share-based compensation.

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

| | Three Months Ended March 31, | |
|---|---|---|
| **(US$ in thousands)** | **2012** | **2011** |
| Cost of sales | $ 177 | $ 40 |

| | | | | |
|---|---|---|---|---|
| Sales and marketing | | 448 | | 628 |
| General and administrative | | 813 | | 790 |
| Research and development | | 42 | | 51 |
| | | | | |
| Total | $ | 1,480 | $ | 1,509 |

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

During the three months ended March 31, 2012 and 2011, there were 262,713 and 296,487 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

**13. Income taxes**

The Company recognized a $7.1 million and $6.3 million provision for income tax which reflects an effective tax rate of 37% and (21%) for the three months ended March 31, 2012 and 2011, respectively. The effective tax rate for the first quarter of 2011 was 38% excluding the impact of the discrete charges related to the U.S. Government resolutions for which no benefit was recorded. For 2011 the Company did not record a tax benefit on certain expenses associated with the Company s estimate of the charges related to U.S. Government resolutions. The difference between the rates of 37% and 38% is driven by 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 March 31, 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 within its global operations in income tax expense. The Company had approximately $0.5 million accrued for payment of interest and penalties as of March 31, 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 March 31, 2012, the Company does not expect the amount of unrecognized tax benefits to change significantly over the next twelve months.

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

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.

**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 three GBUs, which are comprised of Spine, Orthopedics and Sports Medicine 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 three 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 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 orthopedics products to hospitals, doctors and other healthcare providers, globally.

*Sports Medicine*

Sports Medicine designs, manufactures and distributes a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Sports Medicine distributes products through a network of domestic and international distributors, sales representatives and affiliates to hospitals, doctors and other healthcare providers, primarily in the U.S.

*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 three GBUs.

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

*Segment Information*

The table below presents external net sales by market sector:

| | External Net Sales by Market Sector Three Months Ended March 31, | | | |
|---|---|---|---|---|
| **(US$ in thousands)** | **2012** | **2011** | **Reported Growth** | **Constant Currency Growth** |
| Spine Products | | | | |
| Spine Repair Implants and Regenerative Biologics | $ 35,757 | $ 33,957 | 5% | 5% |
| Spine Regenerative Stimulation | 39,271 | 38,618 | 2% | 2% |
| Total Spine Products | 75,028 | 72,575 | 3% | 3% |
| Orthopedics Products | 41,014 | 40,485 | 1% | 4% |
| Sports Medicine Products | 27,099 | 24,731 | 10% | 10% |
| Total Strategic Products | 143,141 | 137,791 | 4% | 5% |
| Divested Products (1) | | 1,374 | (100)% | (100)% |
| Total Net Sales | $ 143,141 | $ 139,165 | 3% | 4% |

(1) Divested Products sales for the three months ended March 31, 2011 include approximately $1.4 million, related to the vascular business which was divested in March 2010 and is part of the Sports Medicine GBU.

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

| Operating Income (Loss) by GBU (US$ in thousands) | Three Months Ended March 31, 2012 | 2011 |
|---|---|---|
| Spine(1) | $ 21,564 | $ (16,426) |
| Orthopedics(2) | 4,979 | (3,632) |
| Sports Medicine(3) | (10) | 1,445 |
| Corporate (4) | (4,489) | (7,448) |
| | | |
| Total | $ 22,044 | $ (26,061) |

(1) For the three months ended March 31, 2011, the operating loss for the Spine GBU included $36.5 million and $3.3 million of expenses in connection with charges related to U.S. Government resolutions and associated legal costs, respectively. Operating income for the three months ended March 31, 2012 included $0.8 million of research and development costs related to the Company s investment in the Musculoskeletal Transplant Foundation ( MTF ).

(2) For the three months ended March 31, 2011, the operating loss for the Orthopedics GBU included $6.5 million and $1.1 million of expenses in connection with charges related to U.S. Government resolutions and associated legal costs, respectively. Operating income for the three months ended March 31, 2012 included $0.2 million of research and development costs related to the Company s investment in MTF.

(3) For three months ended March 31, 2012, the operating income for the Sports Medicine GBU included $1.8 million of litigation and settlement costs for certain product liability matters and $0.3 million of legal costs related to the sale of the Company s Sports Medicine GBU.

(4) For the three months ended March 31, 2011, the operating loss for the Corporate GBU included $3.0 million of expenses in connection with charges related to U.S. Government inquiries.

**15. 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 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.

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

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 reasonable estimable. As of March 31, 2012, the Company has recognized an aggregate accrual of $1.3 million for such additional matters. The Company believes additional 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 Department of Health and Human Services, Office of Inspector General ( 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 intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

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 the 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 the 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 the 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 the 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 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 the OIG, as to the terms of definitive written agreements to finally resolve these matters.

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

As part of the resolution of this matter (and matters described below related to the Company s regenerative stimulation business), the Company expects that the Company, Orthofix Inc. and Blackstone will enter into a five-year Corporate Integrity Agreement with the 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.

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.

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.

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 supplemental subpoenas seeking documents in this matter, dated September 21, 2009, December 16, 2009, October 13, 2010, October 14, 2010, October 18, 2010, December 3, 2010 and

January 13, 2011, respectively. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. The Boston USAO also issued two supplemental subpoenas requiring testimony in this matter dated July 23, 2009 and June 3, 2010. That office excused performance with the July 23, 2009 subpoena indefinitely. The Boston USAO has provided the Company with grand jury subpoenas for the testimony of certain current and former employees in connection with its ongoing investigation. The Company has been cooperating, and intends to continue to cooperate, with the government s 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. By order entered on March 24, 2009, the court unsealed the case. The Company and Orthofix Inc. were served on or about September 8, 2009. With leave of the court, the relator s Second Amended Complaint was filed on June 11, 2010. The complaint alleges 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 includes 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. The Company believes that this lawsuit is related to the matter described above involving the HIPAA subpoena. On or about December 4, 2010, the U.S. District Court for the District of Massachusetts denied the Company s motion to dismiss.

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. The Company is currently finalizing definitive written agreements with the Boston USAO, the DOJ, and the OIG to finally resolve these matters. The Company expects that under the terms of these agreements, it will pay $43 million, and the Company has recorded a charge of $43 million during the first quarter of 2011 in anticipation of this agreement. The Company expects that (i) its subsidiary, Orthofix Inc., will plead to a violation of 18 U.S.C. 1516 (obstruction of federal audit) related to a June 2008 federal audit, and (ii) the Company, Orthofix Inc. and Blackstone Medical, Inc. will enter into a five-year Corporate Integrity Agreement with the OIG as part of the resolution of these matters (and the matters related to Blackstone Medical, Inc. described above).

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

Based on information currently available, the Company believes that it is probable that a final definitive written settlement agreement with the U.S. Government will be entered into on these terms. The Company has therefore recognized an accrual for $43 million during the first quarter of 2011. 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.

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, allegedly made 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 the 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. On or about November 16, 2010, the Company received a subpoena from the SEC and DOJ seeking documents related to this matter. The Company has completed its production of documents to the SEC and DOJ in connection with the subpoena.

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. The Company is currently in discussions with the DOJ as to the final terms of such resolution, and is also currently engaged in discussions regarding a settlement of such matters with the SEC. The Company recorded a charge related to these matters of $3.0 million during the first quarter of 2011, and subsequently recorded an additional charge of $4.5 million during the fourth quarter of 2011 to establish an additional accrual in anticipation of a future final resolution of these matters with both the DOJ and the SEC. 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.

Matters Related to Breg

The Company s subsidiary, Breg, Inc. ( Breg ), was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008, when the product line was divested. 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. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with these matters.

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. Document production in response to the subpoena is ongoing.

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 currently cannot reasonably estimate a possible loss, or range of loss, in connection with these matters.

Breg is currently engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Beginning in 2010, several domestic product liability cases have been filed, 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. 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. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

On April 23, 2012, the Company s subsidiary Orthofix Holdings, Inc. ( 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 have agreed to indemnify Buyer 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. At the closing of the Transaction, Buyer will pay to Orthofix Holdings $157.5 million in cash, subject to certain adjustments based on the working capital and indebtedness of Breg at the closing. As a result of the Transaction, the Company will exit its Sports Medicine global business unit, of which Breg was a significant component. The Sports Medicine global business unit contributed $27.1 million and $26.1 million of net sales in the three months ended March 31, 2012 and 2011, respectively. The Sports Medicine global business unit had a small operating loss and earned $1.4 million of operating income in the three months ended March 31, 2012 and 2011, respectively.

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**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 months ended March 31, 2012 compared to our results of operations for the three months ended March 31, 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 along with offering a portfolio of non-invasive products to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility. 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, limb lengthening and bone reconstruction; and bracing products used for ligament injury prevention, pain management and protection of surgical repair to promote faster healing. Our products also include cold therapy, bone cement and devices for removal of bone cement used to fix artificial implants.

We have administrative and training facilities in the United States ( U.S. ) and Italy and manufacturing facilities in the U.S., the United Kingdom, Italy and Mexico. 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 level of such procedures performed in the late summer. Certain of the Breg ® bracing products experience greater demand in the fall and winter corresponding with high school and college football schedules and winter sports. 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 three GBUs, which are comprised of Spine, Orthopedics and Sports Medicine 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 three 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 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 spine products to hospitals, doctors and other healthcare providers, globally.

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*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 orthopedics products to hospitals, doctors and other healthcare providers, globally.

*Sports Medicine*

Sports Medicine designs, manufactures and distributes a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Sports Medicine distributes products through a network of domestic and international distributors, sales representatives and affiliates to hospitals, doctors and other healthcare providers, primarily in the U.S.

*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 three GBUs.

**GBU and Market Sector Revenues**

The following table displays net sales by market sector for the three months ended March 31, 2012 and 2011. We assess our performance based on these GBUs and market sectors. We maintain our records and account for net sales, costs of sales and expenses by GBU.

| | External Net Sales by Market Sector Three Months Ended March 31, | | | |
|---|---|---|---|---|
| **(US$ in thousands)** | **2012** | **2011** | **Reported Growth** | **Constant Currency Growth** |
| Spine Products | | | | |
| Spine Repair Implants and Regenerative Biologics | $ 35,757 | $ 33,957 | 5% | 5% |
| Spine Regenerative Stimulation | 39,271 | 38,618 | 2% | 2% |
| Total Spine Products | 75,028 | 72,575 | 3% | 3% |
| Orthopedics Products | 41,014 | 40,485 | 1% | 4% |

| | | | | |
|---|---|---|---|---|
| Sports Medicine Products | 27,099 | 24,731 | 10% | 10% |
| Total Strategic Products | 143,141 | 137,791 | 4% | 5% |
| Divested Products (1) | | 1,374 | (100)% | (100)% |
| Total Net Sales | $ 143,141 | $ 139,165 | 3% | 4% |

(1) Divested Products sales for the three months ended March 31, 2011 include approximately $1.4 million, related to the vascular business which was divested in March 2010 and is part of the Sports Medicine GBU.

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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 March 31, | |
|---|---|---|
| | 2012 (%) | 2011 (%) |
| Net sales | 100 | 100 |
| Cost of sales | 23 | 24 |
| Gross profit | 77 | 76 |
| Operating expenses: | | |
| Sales and marketing | 41 | 40 |
| General and administrative | 15 | 17 |
| Research and development | 5 | 4 |
| Amortization of intangible assets | 1 | 1 |
| Charges related to U.S. Government resolutions | | 33 |
| Operating income (loss) | 15 | (19) |
| Net income (loss) | 8 | (26) |

**Three Months Ended March 31, 2012 Compared to Three Months Ended March 31, 2011**

Net sales increased $3.9 million to $143.1 million in the first quarter of 2012 compared to $139.2 million for the same period last year. The impact of foreign currency decreased sales by $1.3 million during the first quarter of 2012 when compared to the first quarter of 2011.

*Sales*

Net sales in our Spine market sector increased to $75 million in the first quarter of 2012 compared to $72.6 million for the same period last year, an increase of $2.4 million. The increase in Spine s net sales was primarily the result of a 5% increase in sales of our repair implants and regenerative biologics revenue products in the first quarter 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 45% increase in sales of regenerative biologics in the first quarter of 2012. The regenerative stimulations products used in Spine applications increased 2% when compared to the prior year.

Net sales in our Orthopedics market sector increased 1%, (or 4% on a constant currency basis) to $41 million in the first quarter of 2012 compared to $40.5 million for the same period last year. This increase was led by our internal and external fixation product offerings in international markets, along with an 8% increase in regenerative biologics partially offset by lower long-bone stimulation sales. Adding to the increase was the Galaxy Fixation System that was launched in international markets and the Ankle Compression Nailing and Lapidus Plating Systems that were launched in the U.S.

Net sales in our Sports Medicine market sector increased to $27.1 million in the first quarter of 2012 compared to $24.7 million for the same period in the prior year, an increase of 10%. The first quarter of 2012 and 2011 included revenues of $1.4 million and $0.5 million, respectively, resulting from the acquisition of Omni Motion, Inc. The increase was also due to increased volume and favorable pricing of bracing products.

Net sales of our Divested Products for the three months ended March 31, 2011 include $1.4 million related to the vascular business which we divested in March 2010. This revenue represents amounts recognized in the first quarter 2011 from the transition services supply agreement that commenced upon the sale of the business. There were no related sales in the first quarter of 2012.

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*Gross Profit* Our gross profit increased $4.5 million to $110.3 million in the first quarter of 2012, compared to $105.8 million for the same period last year. Gross profit as a percent of net sales in the first quarter of 2012 was 77% compared to 76% for the same period last year. The improvement in the gross profit margin is primarily a result of a favorable product and geographical sales mix.

*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 $2.7 million, to $58.3 million in the first quarter of 2012 compared to $55.6 million in the first quarter of 2011. As a percent of net sales, sales and marketing expense was 41% and 40% in the first quarter of 2012 and 2011, respectively.

*General and Administrative Expense* General and administrative expense decreased $2.1 million, or 9%, in the first quarter of 2012 to $20.9 million compared to $23.0 million in the first quarter of 2011. General and administrative expense as a percent of net sales was 14.6% in the first quarter of 2012 compared to 16.5% for the same period last year. The decrease in general and administrative expense relates to decreased legal costs associated with various legal matters. During the first quarter of 2011, we incurred $4.4 million and $0.6 million of expenses related to the industry wide bone growth stimulation and Mexico FCPA investigations, respectively. The first quarter of 2012 included $1.8 million of litigation and settlement costs for certain product liability matters related to our Sports Medicine GBU, and approximately $0.7 in legal costs related to the final activities associated with the U.S. Government resolutions.

*Research and Development Expense* Research and development expense increased $1.6 million in the first quarter of 2012 to $7.7 million compared to $6.1 million for the same period last year. As a percent of sales, research and development expense was 5.4% in the first quarter of 2012 compared to 4.3% for the same period last year. The increase in research and development expenses in the first quarter of 2012 compared to the same period in the prior year was due to our 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 decreased by $0.1 million in the first quarter of 2012 to $1.2 million compared to $1.3 million for the same period last year.

*Charges Related to U.S. Government Resolutions* During 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. The Company is finalizing definitive agreements with the U.S. Attorney s Office, the DOJ, and the OIG to resolve these matters which includes resolution of a qui tam lawsuit pending in the U.S. District Court for the District of Massachusetts. We expect that under the terms of these agreements, the Company will pay $43 million to resolve these matters, and we have recorded a charge of $43 million in anticipation of these agreements. We expect that (i) our subsidiary, Othofix Inc., will plead to a violation of 18 U.S.C. 1516 (obstruction of federal audit) related to a June 2008 federal audit, and (ii) Orthofix International N.V. and Orthofix Inc will enter into a five-year Corporate Integrity Agreement ( CIA ) with the OIG as part of the resolution of these matters.

During the first quarter of 2011, we recorded a charge of $3 million to establish an accrual in connection with the potential fines and penalties related to the FCPA matter involving our Promeca subsidiary, and are in discussions with the SEC and DOJ regarding a resolution of this matter. Final resolution is subject to the negotiation and execution of definitive agreements with the DOJ and SEC.

Although neither of these matters has concluded, we believe that the costs for which the charges have been recognized during 2011 are probable of being incurred and paid during 2012. We have recorded these charges associated with the potential settlement costs as charges related to U.S. Government resolutions in our consolidated statements of operations.

*Interest Expense, net* Interest expense, net was $2.2 million for the first quarter of 2012 compared to $2.4 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.

*Other Expense* Other expense was $0.7 million and $1.1 million for the first 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 was 37% and (21%) during the first quarters of 2012 and 2011, respectively. The effective tax rate for the first quarter of 2012 was affected by the mix of earnings among various tax jurisdictions and losses incurred in a number of foreign jurisdictions, for which we do not currently recognize 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 quarter of 2011 was impacted by discrete charges related to U.S. Government inquiries, 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 quarter of 2011 we did not record a tax benefit associated with the expense attributable to the charges related to U.S. Government inquiries 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 quarter of 2011 was 38% excluding the impact of the discrete charges related to U.S. Government inquiries for which no benefit was recorded.

*Net Income* Net income for the first quarter of 2012 was $12 million, or $0.64 per basic and $0.63 per diluted share, compared to net loss of $35.8 million, or ($2.00) per basic and diluted share for the same period last year.

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**Liquidity and Capital Resources**

Cash and cash equivalents including Restricted Cash at March 31, 2012 were $126.4 million, of which $79.4 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of $80.3 million at December 31, 2011, of which $47.1 million was subject to certain restrictions under the senior secured credit agreement discussed below.

Net cash provided by operating activities was $49 million and $18.8 million for the three months ended March 31, 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 and changes in working capital. Net income increased $47.8 million to net income of $12 million for the three months ended March 31, 2012 from a net loss of ($35.8) million for the comparable period in the prior year. Non-cash items for the three months ended March 31, 2012 decreased $1.9 million to $7.8 million compared to non-cash items of $9.7 million in the same period of 2011. Working capital accounts provided $29.1 million and $44.9 million of cash for the three months ended March 31, 2012 and 2011, respectively. For the three months ended March 31, 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. Amounts received from the escrow account will be offset once settlements included in accrued liabilities are ultimately paid. For the three months ended March 31, 2011, working capital accounts were impacted by charges related to U.S. Government resolutions of $46.0 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 99 days at March 31, 2012 and 87 days at March 31, 2011 and inventory turns of 1.4 times at both March 31, 2012 and 2011. The increase in DSO during the period was partially related to the additional working capital investment made associated with our MTF partnership.

Net cash used in investing activities was $6.5 million for the three months ended March 31, 2012 compared to net cash used in investing activities of $10.9 million for the three months ended March 31, 2011. During the first 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 three months ended March 31, 2012 and 2011, we invested $6.5 million and $5.7 million in capital expenditures, respectively.

Net cash used in financing activities was $28.9 million for the three months ended March 31, 2012 compared to net cash provided by financing activities of $1.8 million for the three months ended March 31, 2011. During the three months ended March 31, 2012, we repaid approximately $3.75 million against the principal on our senior secured term loan compared to $1.25 million during the three months ended March 31, 2011. Our restricted cash balance usage increased $29.9 million to $32.3 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 three months ended March 31, 2012 and 2011, we received proceeds of $6.6 million and $7.3 million, respectively, from the issuance of 262,713 shares and 296,487 shares, respectively, of our common stock related to stock purchase plan issuances and stock option exercises.

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

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

As of March 31, 2012 and December 31, 2011, we had $87.5 million and $91.3 million, respectively, 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 March 31, 2012 and December 31, 2011, the entire Term Loan Facility of $87.5 million and $91.3 million, respectively, was at the LIBOR rate plus a margin of 3.00%. In addition, as of March 31, 2012 and December 31, 2011, $100.0 million of the Revolving Credit Facility was at the LIBOR rate plus a margin of 3.00% and 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 March 31, 2012 and December 31, 2011 was 3.4%.

The principal amount of the Term Loan Facility amortizes at the rate of 5%, 15%, 25%, 25% and 30% in year 1, 2, 3, 4 and 5, respectively. Amortization payments began on December 31, 2010 and end on December 31, 2015. Outstanding principal on the Revolving Credit Facility is due on December 31, 2015.

Borrowings under the Revolving Credit Facility, which may be made in the future, will be used for working capital, capital expenditures and other general corporate purposes of Orthofix Holdings and its subsidiaries. The Guarantors have guaranteed repayment of Orthofix Holdings obligations under the Credit Agreement. The obligations of Orthofix Holdings and each of the Guarantors with respect to the Credit Facilities are secured by a pledge of substantially all of the assets of Orthofix Holdings and each of the Guarantors.

In May 2011, we obtained an amendment to the Credit Agreement to provide additional capacity under the various restrictive negative covenants for our payment of the Specified Settlement Amounts (as defined in the Credit Agreement, as amended) associated with each of the potential settlements (See Note 15 to the Unaudited Condensed Consolidated Financial Statements). The amendment updates the definition of Consolidated EBITDA to exclude Specified Settlement Amounts of up to $50 million in the aggregate. 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 March 31, 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.

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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 March 31, 2012 and December 31, 2011 was $187.2 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 March 31, 2012 and December 31, 2011 was $79.4 million and $47.1 million, respectively.

In conjunction with obtaining the Credit Facilities and the Credit Agreement, as amended, we incurred debt issuance costs of $5.0 million. These costs are being amortized using the effective interest method over the life of the Credit Facilities. As of March 31, 2012 and December 31, 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement and the Credit Agreement, as amended, were $3.2 million and $3.5 million, respectively.

At March 31, 2012, we had outstanding borrowings of 1.1 million ($1.4 million) and unused available lines of credit of approximately 6.2 million ($8.3 million) under lines 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 $82.6 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.

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**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 March 31, 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 March 31, 2012, the entire Term Loan Facility of $87.5 million and $100 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00%. The remaining $17.4 million of the Revolving Credit Facility is at a base (as defined in the Credit Agreement, as amended) plus a margin of 2.00%. These margins are adjusted based upon the measurement of the consolidated leverage ratio of our Company and our subsidiaries with respect to the immediately preceding four fiscal quarters. As of March 31, 2012, our effective interest rate on our Credit Facilities was 3.4%. Based on the balance outstanding under the Credit Facilities as of March 31, 2012, an immediate change of one percentage point in the applicable interest rate on the Term Loan Facility and Revolving Credit Facility would cause a change in interest expense of approximately $2.0 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 March 31, 2012, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million ($31.0 million). We recorded an unrealized foreign currency gain during the three months ended March 31, 2012 of less than $0.9 million related to this un-hedged long-term intercompany note, which resulted from the strengthening of the Euro against the U.S. dollar 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 three months ended March 31, 2012, we recorded a foreign currency loss of $0.6 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.

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**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 March 31, 2012 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

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**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 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 reasonable estimable. As of March 31, 2012, we recognized an aggregate accrual of $1.3 million for such additional matters. We believe additional 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 Department of Health and Human Services, Office of Inspector General ( 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 intends to contest it in accordance with the terms of the Blackstone Merger Agreement. 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 the 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.

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We believe that the subpoena concerned the compensation of physician consultants and related matters, and further believe that it was associated with the 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 the 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 the 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 the OIG, the Boston USAO, and the 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, the DOJ, and the 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), we expect that Orthofix International N.V., Orthofix Inc. and Blackstone Medical, Inc. will enter into a five-year Corporate Integrity Agreement with the 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.

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.

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.

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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 supplemental subpoenas seeking documents in this matter, dated September 21, 2009, December 16, 2009, October 13, 2010, October 14, 2010, October 18, 2010, December 3, 2010 and January 13, 2011, respectively. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. The Boston USAO also issued two supplemental subpoenas requiring testimony in this matter dated July 23, 2009 and June 3, 2010. That office excused performance with the July 23, 2009 subpoena indefinitely. The Boston USAO has provided us with grand jury subpoenas for the testimony of certain current and former employees in connection with its ongoing investigation. We have been cooperating, and intend to continue to cooperate, with the government s 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. By order entered on March 24, 2009, the court unsealed the case. We and Orthofix Inc. were served on or about September 8, 2009. With leave of the court, the relator s Second Amended Complaint was filed on June 11, 2010. The complaint alleges 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 includes 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. We believe that this lawsuit is related to the matter described above involving the HIPAA subpoena. On or about December 4, 2010, the U.S. District Court for the District of Massachusetts denied our motion to dismiss.

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. We are currently finalizing definitive written agreements with the Boston USAO, the DOJ, and the OIG to finally resolve these matters. We expect that under the terms of these agreements, we will pay $43 million, and we recorded a charge of $43 million during the first quarter of 2011 in anticipation of this agreement. We expect that (i) our subsidiary, Orthofix Inc., will plead to a violation of 18 U.S.C. 1516 (obstruction of federal audit) related to a June 2008 federal audit, and (ii) Orthofix International N.V., Orthofix Inc. and Blackstone Medical, Inc. will enter into a five-year Corporate Integrity Agreement (CIA) with the OIG as part of the resolution of these matters (and the matters related to Blackstone Medical, Inc. described above). Based on information currently available, we believe that it is probable that a final definitive written settlement agreement with the U.S. Government will be entered into on these terms. We have therefore recognized an accrual for this amount during the first quarter of 2011. 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.

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, allegedly made 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 the 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. On or about November 16, 2010, we received a subpoena from the SEC and DOJ seeking documents related to this matter. We have completed our production of documents to the SEC and DOJ in connection with the subpoena.

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 the DOJ. We are currently in discussions with the DOJ as to the final terms of such resolution, and are also currently engaged in discussions regarding a settlement of such matters with the SEC. We previously recorded a charge related to these matters of $3.0 million during the first quarter of 2011, and subsequently recorded an additional charge of $4.5 million during the fourth quarter of 2011 to establish an additional accrual in anticipation of a future final resolution of these matters with both the DOJ and the SEC. 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.

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Matters Related to Breg

Our subsidiary, Breg, Inc ( Breg ), was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008, when the product line was divested. 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. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with these matters.

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. Document production in response to the subpoena is ongoing. 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 currently cannot reasonably estimate a possible loss, or range of loss, in connection with these matters.

Breg is currently engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Beginning in 2010, several domestic product liability cases have been filed, 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. 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. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

On April 23, 2012, our subsidiary Orthofix Holdings, Inc. ( 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. Under the terms of the SPA, upon closing of the sale, we and Orthofix Holdings have agreed to indemnify Buyer 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.

On April 23, 2012, the Company s subsidiary Orthofix Holdings, Inc. ( 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 have agreed to indemnify Buyer 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. At the closing of the Transaction, Buyer will pay to Orthofix Holdings $157.5 million in cash, subject to certain adjustments based on the working capital and indebtedness of Breg at the closing. As a result of the Transaction, the Company will exit its Sports Medicine global business unit, of which Breg was a significant component. The Sports Medicine global business unit contributed $27.1 million and $26.1 million of net sales in the three months ended March 31, 2012 and 2011, respectively. The Sports Medicine global business unit had a small operating loss and earned $1.4 million of operating income in the three months ended March 31, 2012 and 2011, respectively.

**ITEM 1A. RISK FACTORS**

There have been no material changes to our risk factors from the factors discussed in Part I, Item 1A. *Risk Factors* in our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2011.

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**Item 6. Exhibits**

| Exhibit Number | Description |
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| 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 BrasilLtda, 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, OrthofixS.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. 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). |

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| 10.8 | 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). |

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| 10.9 | Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company s current report on Form 8-K filed January 7, 2009, and incorporated herein by reference). |
| 10.10 | Form of Employee Non-Qualified Stock Option Agreement (post-2008 grants) (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 and incorporated herein by reference). |
| 10.11 | Form of Non-Employee Director Non-Qualified Stock Option Agreement (post-2008 grants) (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 and incorporated herein by reference). |
| 10.12 | Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants vesting over 3 years) (filed as an exhibit to the Company s current report on Form 8-K filed June 20, 2008 and incorporated herein by reference). |
| 10.13 | Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants 3 year cliff vesting) (filed as an exhibit to the Company s current report on Form 8-K filed June 20, 2008 and incorporated herein by reference). |
| 10.14 | Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2011 grants vesting over 3 years) (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 Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (post-2010 grants vesting over 3 years) (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). |
| 10.16 | Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff vesting) (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 | 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 8-K of Orthofix International N.V dated September 10, 2008 and incorporated herein by reference). |
| 10.18 | Inducement Grant Nonqualified Stock Option Agreement, dated April 1, 2011, between Orthofix International N.V. 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). |

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| 10.19 | 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). |
| 10.20 | 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). |
| 10.21 | 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). |
| 10.22 | Description of Director Compensation Policy (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). |
| 10.23 | 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). |
| 10.24 | 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). |
| 10.25 | 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). |
| 10.26 | 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). |
| 10.27 | 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). |
| 10.28 | 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). |
| 10.29 | 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). |
| 10.30 | 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). |

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| 10.31 | 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). |
| 10.32 | 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). |
| 10.33 | Amended and Restate Employment Agreement, entered into on February 11, 2011, by and between Breg, Inc. and Brad Lee (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). |
| 10.34 | 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). |
| 10.35 | 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). |
| 10.36 | 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). |
| 10.37 | 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 incorporatetd herein by reference). |
| 10.38 | 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). |
| 10.39 | 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). |

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| 10.40 | 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). |
| 10.41 | 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). |
| 10.42 | 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). |
| 31.1* | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer. |
| 31.2* | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer. |
| 32.1* | Section 1350 Certification of Chief Executive Officer. |
| 32.2* | Section 1350 Certification of Chief Financial Officer. |
| 101* | The following materials from the Orthofix International N.V. Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 formatted in Extensible Business Reporting Language ( XBRL ): (i) Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the 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.

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**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.

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| Date: May 4, 2012 | By: | /s/ Robert S. Vaters | |
| | | Name: | Robert S. Vaters |
| | | Title: | President and Chief Executive Officer |
| Date: May 4, 2012 | By: | /s/ Brian McCollum | |
| | | Name: | Brian McCollum |
| | | Title: | Senior Vice President of Finance and Chief Financial Officer |