

ORTHOFIX INTERNATIONAL N V

Form 10-Q

May 10, 2011

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(Mark one)

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

For the quarterly period ended March 31, 2011

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 0-19961

**ORTHOFIX INTERNATIONAL N.V.**

(Exact name of registrant as specified in its charter)

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**Curaçao**  
(State or other jurisdiction of  
incorporation or organization)

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

**7 Abraham de Veerstraat**

**Curaçao**  
(Address of principal executive offices)

**Not applicable**  
(Zip Code)

**599-9-4658525**

(Registrant's telephone number, including area code)

**Not applicable**

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

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

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

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

Large Accelerated filer  Accelerated filer

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

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

As of May 4, 2011, 18,055,017 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, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans, anticipates, believes, estimates, projects, intends, predicts, potential or continue or other comparable 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, the resolution of pending litigation matters (including the government investigation relating to our bone growth stimulation business and the possible violations of the FCPA by our former Mexican orthopedic distribution entity), changing relationships with customers, suppliers, strategic partners and lenders, changes to and the interpretation of governmental regulations, 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 for the year ended December 31, 2010, under Item 1A., "Risk Factors."

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements****ORTHOFIX INTERNATIONAL N.V.****Condensed Consolidated Balance Sheets**

| (U.S. Dollars, in thousands except share data)  | March 31,<br>2011<br>(unaudited) | December 31,<br>2010 |
|---|----------------------------------|----------------------|
| <b>Assets</b>   |                                  |                      |
| Current assets:   |                                  |                      |
| Cash and cash equivalents   | \$ 23,387                        | \$ 13,561            |
| Restricted cash   | 25,432                           | 22,944               |
| Trade accounts receivable, less allowance for doubtful accounts of \$7,636 and \$7,250 at March 31, 2011 and December 31, 2010, respectively                            | 133,929                          | 134,184              |
| Inventories, net  | 93,666                           | 84,589               |
| Deferred income taxes   | 18,332                           | 17,422               |
| Escrow receivable   | 15,225                           | 14,937               |
| Prepaid expenses and other current assets   | 22,351                           | 24,123               |
| Total current assets  | 332,322                          | 311,760              |
| Property, plant and equipment, net  | 48,113                           | 45,535               |
| Patents and other intangible assets, net  | 40,372                           | 41,457               |
| Goodwill  | 182,290                          | 176,497              |
| Deferred income taxes   | 16,222                           | 16,175               |
| Other long-term assets  | 11,965                           | 12,565               |
| Total assets  | \$ 631,284                       | \$ 603,989           |
| <b>Liabilities and shareholders' equity</b>   |                                  |                      |
| Current liabilities:  |                                  |                      |
| Bank borrowings   | \$ 2,020                         | \$ 3,812             |
| Current portion of long-term debt   | 10,000                           | 7,500                |
| Trade accounts payable  | 20,584                           | 19,796               |
| Accrued charges related to U.S. Government inquiries  | 46,000                           |                      |
| Other current liabilities   | 56,972                           | 52,418               |
| Total current liabilities   | 135,576                          | 83,526               |
| Long-term debt  | 204,945                          | 208,695              |
| Deferred income taxes   | 7,819                            | 8,102                |
| Other long-term liabilities   | 5,861                            | 2,775                |
| Total liabilities   | 354,201                          | 303,098              |
| Contingencies (Note 17)   |                                  |                      |
| Shareholders' equity:   |                                  |                      |
| Common shares \$0.10 par value; 50,000,000 shares authorized; 18,023,132 and 17,726,645 issued and outstanding as of March 31, 2011 and December 31, 2010, respectively | 1,802                            | 1,772                |
| Additional paid-in capital  | 204,275                          | 195,402              |
| Retained earnings   | 62,526                           | 98,327               |
| Accumulated other comprehensive income  | 8,480                            | 5,390                |
| Total shareholders' equity  | 277,083                          | 300,891              |

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|  |            |            |
|--|------------|------------|
| Total liabilities and shareholders' equity | \$ 631,284 | \$ 603,989 |
|--|------------|------------|

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

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****Condensed Consolidated Statements of Operations****For the three months ended March 31, 2011 and 2010**

| (Unaudited, U.S. Dollars, in thousands except share and per share data) | Three Months Ended |                   |
|---|--------------------|-------------------|
|   | 2011               | March 31,<br>2010 |
| Net sales   | \$ 139,165         | \$ 138,823        |
| Cost of sales   | 33,361             | 32,694            |
| Gross profit  | 105,804            | 106,129           |
| Operating expenses  |                    |                   |
| Sales and marketing   | 55,598             | 56,290            |
| General and administrative  | 22,960             | 21,470            |
| Research and development  | 6,052              | 7,528             |
| Amortization of intangible assets                                       | 1,255              | 1,447             |
| Gain on sale of vascular operations (Note 16)                           |                    | (12,551)          |
| Charges related to U.S. Government inquiries (Note 18)                  | 46,000             |                   |
|   | 131,865            | 74,184            |
| Operating (loss) income   | (26,061)           | 31,945            |
| Other income (expense)  |                    |                   |
| Interest expense, net   | (2,416)            | (5,846)           |
| Gain on interest rate swap  |                    | 345               |
| Other expense, net  | (1,073)            | (330)             |
|   | (3,489)            | (5,831)           |
| (Loss) income before income taxes                                       | (29,550)           | 26,114            |
| Income tax expense  | (6,251)            | (8,622)           |
| Net (loss) income   | \$ (35,801)        | \$ 17,492         |
| Net (loss) income per common share:                                     |                    |                   |
| Basic   | \$ (2.00)          | \$ 1.00           |
| Diluted   | \$ (2.00)          | \$ 0.99           |
| Weighted average number of common shares:                               |                    |                   |
| Basic   | 17,937,280         | 17,489,315        |
| Diluted   | 17,937,280         | 17,757,099        |

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



**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****Condensed Consolidated Statements of Cash Flows****For the three months ended March 31, 2011 and 2010**

| (Unaudited, U.S. Dollars, in thousands)  | Three Months Ended<br>March 31, |                 |
|--|---------------------------------|-----------------|
|  | 2011                            | 2010            |
| Cash flows from operating activities:  |                                 |                 |
| Net (loss) income  | \$ (35,801)                     | \$ 17,492       |
| Adjustments to reconcile net (loss) income to net cash provided by operating activities:                           |                                 |                 |
| Depreciation and amortization  | 5,339                           | 5,398           |
| Amortization of debt costs   | 249                             | 54              |
| Provision for doubtful accounts  | 1,833                           | 1,716           |
| Deferred income taxes  | (856)                           | (1,417)         |
| Share-based compensation   | 1,509                           | 3,013           |
| Provision for inventory obsolescence   | 798                             | 2,868           |
| Gain on interest rate swap   |                                 | (345)           |
| Gain on sale of vascular operations  |                                 | (12,551)        |
| Tax benefit on non-qualified stock options   | (585)                           | (1,628)         |
| Other  | 1,379                           | 489             |
| Change in operating assets and liabilities, net of effect of gain on sale of vascular operations and acquisitions: |                                 |                 |
| Trade accounts receivable  | 1,257                           | (8,407)         |
| Inventories  | (7,958)                         | (66)            |
| Prepaid expenses and other current assets  | 1,719                           | (2,882)         |
| Trade accounts payable   | 185                             | (1,313)         |
| Charges related to U.S. Government inquiries   | 46,000                          |                 |
| Other current liabilities  | 3,711                           | 1,520           |
| <b>Net cash provided by operating activities</b>   | <b>18,779</b>                   | <b>3,941</b>    |
| Cash flows from investing activities:  |                                 |                 |
| Capital expenditures for property, plant and equipment   | (5,547)                         | (4,274)         |
| Capital expenditures for intangible assets   | (106)                           | (79)            |
| Payment made in connection with acquisition  | (5,250)                         |                 |
| Net proceeds from sale of vascular operations  |                                 | 24,193          |
| <b>Net cash (used in) provided by investing activities</b>   | <b>(10,903)</b>                 | <b>19,840</b>   |
| Cash flows from financing activities:  |                                 |                 |
| Net proceeds from issuance of common shares  | 7,326                           | 4,613           |
| Repayments of long-term debt   | (1,250)                         | (19,829)        |
| Repayment of bank borrowings, net  | (1,886)                         | (38)            |
| Change in restricted cash  | (2,442)                         | (4,353)         |
| Cash payment for purchase of minority interest in subsidiary   | (517)                           |                 |
| Tax benefit on non-qualified stock options   | 585                             | 1,628           |
| <b>Net cash provided by (used in) financing activities</b>   | <b>1,816</b>                    | <b>(17,979)</b> |
| Effect of exchange rate changes on cash  | 134                             | (371)           |
| <b>Net increase in cash and cash equivalents</b>   | <b>9,826</b>                    | <b>5,431</b>    |
| Cash and cash equivalents at the beginning of the period   | 13,561                          | 13,328          |



|  |           |           |
|--|-----------|-----------|
| Cash and cash equivalents at the end of the period | \$ 23,387 | \$ 18,759 |
|--|-----------|-----------|

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

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**ORTHOFIX INTERNATIONAL N.V.**

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

**1. Description of business**

Orthofix International N.V. (the Company) is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical equipment. During 2010, the Company was comprised of four reportable segments: Domestic, Spinal Implants and Biologics (formerly referred to as Blackstone), Breg and International. Beginning January 1, 2011, the Company began managing its business by its three global business units (GBUs) comprised of Spine, Orthopedics and Sports Medicine supported by Corporate activities. See Note 14 for a description of each segment.

**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, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. The balance sheet at December 31, 2010 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 for the fiscal year ended December 31, 2010.

**(b) Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year presentation. The reclassifications have no effect on previously reported net earnings or shareholders' equity. Consistent with the December 31, 2010 presentation, the Company has reclassified its changes to restricted cash in the Condensed Consolidated Statements of Cash Flows from operating activities to financing activities for the three months ended 2010. The Company deemed this as a more appropriate disclosure since the cash is restricted for use by only those parties included in the secured revolving credit facility and secured term loan facility entered into on August 30, 2010 (see Note 7). Net cash used in operating activities was previously reported as \$0.4 million for the three months ended March 31, 2010. Beginning January 1, 2011, the Company began managing its business by its three GBUs comprised of Spine, Orthopedics and Sports Medicine. In Note 14, Business Segment Information, there are reclassifications among the GBUs' net sales and operating income for the three months ended March 31, 2010.

**(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 contractual allowances, doubtful accounts, inventories, taxes, shared-based compensation, potential goodwill and intangible asset impairment and loss provision for contingent liabilities. Actual results could differ from these estimates.

**(d) Recently Issued Accounting Standards**

On July 21, 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-20, *Disclosures about the Credit Quality of Financing Receivables and the Allowance for Credit Losses*. This update requires increased



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disclosures about the credit quality of financing receivables and allowances for credit losses, including disclosure about credit quality indicators, past due information and modifications of finance receivables. The Company adopted all amendments that require disclosures as of the end of the reporting period on December 31, 2010. The Company adopted all amendments that require disclosures about activity that occurs during the first quarter reporting period of 2011. The adoption did not have a material impact on the Company's condensed consolidated 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,<br>2011 | December 31,<br>2010 |
|-------------------------------|-------------------|----------------------|
| Raw materials                 | \$ 18,442         | \$ 12,186            |
| Work-in-process               | 6,902             | 5,855                |
| Finished products             | 51,757            | 54,049               |
| Field inventory               | 37,683            | 32,915               |
| Consignment inventory         | 9,064             | 9,009                |
|                               | 123,848           | 114,014              |
| Less reserve for obsolescence | (30,182)          | (29,425)             |
|                               | \$ 93,666         | \$ 84,589            |

**4. Patents and other intangible assets**

| (US\$ in thousands)                                       | March 31,<br>2011 | December 31,<br>2010 |
|---|-------------------|----------------------|
| <b>Cost</b>   |                   |                      |
| Patents and developed technologies                        | \$ 26,448         | \$ 26,226            |
| Trademarks definite lived (subject to amortization)       | 555               | 543                  |
| Trademarks indefinite lived (not subject to amortization) | 23,104            | 23,104               |
| Distribution networks                                     | 44,586            | 44,586               |
|   | 94,693            | 94,459               |
| <b>Accumulated amortization</b>                           |                   |                      |
| Patents and developed technologies                        | (18,852)          | (18,267)             |
| Trademarks definite lived (subject to amortization)       | (364)             | (337)                |
| Distribution networks                                     | (35,105)          | (34,398)             |
| <b>Patents and other intangible assets, net</b>           | \$ 40,372         | \$ 41,457            |

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Amortization expense for intangible assets is estimated to be approximately \$3.8 million for the remainder of 2011 and \$5.0 million, \$2.1 million, \$1.6 million, \$1.1 million and \$3.7 million for the periods ending December 31, 2012, 2013, 2014, 2015 and 2016 and thereafter, respectively.

**Table of Contents****5. Goodwill**

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

| (US\$ in thousands)         | Total      |
|-----------------------------|------------|
| At December 31, 2010        | \$ 176,497 |
| Acquisitions <sup>(1)</sup> | 4,382      |
| Foreign currency            | 1,411      |
| At March 31, 2011           | \$ 182,290 |

- (1) On February 17, 2011, the Company, through its wholly-owned subsidiary, Breg Holdings LLC, purchased 100% of the stock of Omni Motion, Inc. ( Omni Motion ) for a cash purchase price of \$5.3 million plus acquisition costs, which have been recognized as general and administrative expenses in the 2011 condensed consolidated statements of operations. The acquisition and related costs were financed with cash on hand. Omni Motion was privately held when acquired by the Company. The results of Omni Motion's operations have been included in the Company's consolidated results of operations from the date of acquisition. The purchase price has been allocated preliminarily to assets acquired and liabilities assumed based on their estimated fair value at the acquisition date. The Company acquired \$1.5 million of tangible assets and assumed liabilities of \$0.6 million. The Company has recorded the excess purchase price of \$4.4 million to goodwill and is reflected in the Sports Medicine Global Business Unit. The final purchase price allocation is expected to be completed during the second quarter of 2011. Proforma financial information is not required based on the materiality of the acquisition to the Company's condensed consolidated financial statements.

**6. Bank borrowings**

Borrowings under lines of credit consist of borrowings in Euros used to fund international operations. The borrowings under such facility were \$2.0 million and \$3.8 million at March 31, 2011 and December 31, 2010, respectively. The weighted average interest rates on borrowings under lines of credit as of March 31, 2011 and December 31, 2010 were 5.59% and 3.57%, respectively.

The Company had unused available lines of credit of 5.9 million (\$8.3 million) at March 31, 2011 in its Italian line of credit. This line of credit is unsecured and provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

**7. Long-term debt**

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

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

As of March 31, 2011 and December 31, 2010, the Company had \$97.5 million and \$98.8 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. 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.



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As of March 31, 2011 and December 31, 2010, the entire Term Loan Facility of \$97.5 million and \$98.8 million, respectively, is at the LIBOR rate plus a margin of 3.00%. In addition, as of March 31, 2011 and December 31, 2010, \$100.0 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00% and the remaining \$17.4 million of the Revolving Credit Facility is 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, 2011 and December 31, 2010 was 3.4%.

The Credit Agreement requires Orthofix Holdings and the Company to comply with leverage and fixed charge coverage ratios and contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. The Credit Agreement 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 covenants at March 31, 2011.

In May 2011, the Company obtained an amendment to the Credit Agreement (the Amended Credit Agreement) to provide additional capacity under the various restrictive negative covenants for the payment by the Company of the Specified Settlement Amounts (as defined in the Amended Credit Agreement) associated with each of the potential settlements (see Note 18). The amendment updates the definition of Consolidated EBITDA to exclude Specified Settlement Amounts of up to \$50 million in the aggregate. As a result of the Amended Credit Agreement, management believes the Company was in compliance with the negative covenants at March 31, 2011 and there were no events of default. The Company expects to be in compliance with its covenants prospectively.

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, debt repayments and any payment by the Company of the Specified Settlement Amounts as described above. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of March 31, 2011 and December 31, 2010 was \$191.7 million and \$178.5 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities from access to cash held by Orthofix Holdings and its subsidiaries. The amount of restricted cash of the Company as of March 31, 2011 and December 31, 2010 was \$25.4 million and \$22.9 million, respectively.

In conjunction with obtaining the Credit Facilities, the Company incurred debt issuance costs of \$4.3 million which are being amortized using the effective interest method over the life of the Credit Facilities. As of March 31, 2011 and December 31, 2010, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were \$3.7 million and \$3.9 million, respectively.

**8. Derivative instruments**

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

| (US\$ in thousands)            | Fair value:<br>favorable<br>(unfavorable) | Balance sheet location      |
|--------------------------------|---|-----------------------------|
| <b>As of March 31, 2011</b>    |   |                             |
| Cross-currency swap            | \$ (2,368)                                | Other long-term liabilities |
| <b>As of December 31, 2010</b> |   |                             |
| Cross-currency swap            | \$ (262)                                  | Other long-term liabilities |



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| (US\$ in thousands)  | Three Months Ended |          |
|--|--------------------|----------|
|  | 2011               | 2010     |
| Interest rate swap gain recognized in net (loss) income  | \$                 | \$ 345   |
| Cross-currency swap unrealized gain (loss) recorded in other comprehensive (loss) income, net of taxes | \$ 1,102           | \$ (445) |

*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 with JPMorgan Chase Bank and Royal Bank of Scotland PLC (the counterparties) (the replacement swap agreement).

Upon the termination of the cross-currency swap agreement with Wells Fargo on September 30, 2010, 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. As of March 31, 2011 and December 31, 2010, the value of the cash settlement amount was \$0.4 million.

Under the terms of the replacement swap agreement, the Company pays Euros based on a \$38.3 million notional value and a fixed rate of 5.00% and receives U.S. dollars based on a notional value of \$52.0 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 the unrealized gain (loss) on the change in fair value, net of tax, within other comprehensive income.

*Interest rate swap*

In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's former credit facility, the Swap was no longer deemed highly effective. Special hedge accounting was no longer applied and fair value adjustments were reported in current earnings. On June 29, 2010, the Company settled the Swap with the financial institution holder of the derivative instrument. As part of the terms of the buyout of the Swap, the Company paid \$4.8 million to the financial institution holder.

**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

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As of March 31, 2011, the Company held financial instruments including 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. Restricted cash, accounts receivable, short-term bank borrowings and accounts payable approximate fair value due to the short-term maturities of these instruments. The Credit Facilities carry a floating rate of interest, and therefore, the carrying value is considered to approximate the fair value. The derivative instrument is related to the Company's foreign currency hedge of certain intercompany debt.

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 all 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<br>March 31,<br>2011 | Level 1 | Level 2    | Level 3 |
|---|------------------------------|---------|------------|---------|
| Derivative financial instruments <sup>(1)</sup> |                              |         |            |         |
| Cash flow hedges                                |                              |         |            |         |
| Cross-currency hedge                            | \$ (2,368)                   | \$      | \$ (2,368) | \$      |

(1) See Note 8, *Derivative Instruments*.

**10. Comprehensive income (loss)**

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and the effective portion of the gain from the Company's cross-currency swap, which is designated and accounted for as a cash flow hedge (refer to Note 8). The components of and changes in accumulated other comprehensive income were as follows:

| (US\$ in thousands)   | Foreign<br>Currency<br>Translation<br>Adjustments | Fair Value of<br>Cross -Currency<br>Swap | Accumulated<br>Other<br>Comprehensive<br>Income |
|---|---|--|---|
| Balance at December 31, 2010                                | \$ 5,085  | \$ 305                                   | \$ 5,390  |
| Unrealized gain on cross-currency swap, net of tax of \$640 |   | 1,102                                    | 1,102   |
| Foreign currency translation adjustment <sup>(1)</sup>      | 1,988   |  | 1,988   |
| Balance at March 31, 2011                                   | \$ 7,073  | \$ 1,407                                 | \$ 8,480  |

(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.

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Comprehensive (loss) income was comprised of the following components:

| (US\$ in thousands)                                       | Three Months Ended |                  |
|---|--------------------|------------------|
|   | March 31,          |                  |
|   | 2011               | 2010             |
| Net (loss) income   | \$ (35,801)        | \$ 17,492        |
| Other comprehensive (loss) income:                        |                    |                  |
| Unrealized gain (loss) on cross-currency swap, net of tax | 1,102              | (445)            |
| Foreign currency translation adjustment                   | 1,988              | (2,897)          |
| <b>Total comprehensive (loss) income</b>                  | <b>\$ (32,711)</b> | <b>\$ 14,150</b> |

**11. Earnings per share**

For the three months ended March 31, 2011 and 2010, there were no adjustments to net (loss) income for purposes of calculating basic and diluted net (loss) income available to common shareholders. The following is a reconciliation of the weighted average shares used in the basic and diluted net (loss) income per common share computations.

|  | Three Months Ended |                   |
|--|--------------------|-------------------|
|  | March 31,          |                   |
|  | 2011               | 2010              |
| Weighted average common shares-basic                       | 17,937,280         | 17,489,315        |
| Effect of dilutive securities:                             |                    |                   |
| Unexercised stock options net of treasury share repurchase |                    | 267,784           |
| <b>Weighted average common shares-diluted</b>              | <b>17,937,280</b>  | <b>17,757,099</b> |

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 1,783,844 and 1,771,304 outstanding options not included in the diluted earnings per share computation for the three months ended March 31, 2011 and 2010, 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:

| (US\$ in thousands) | Three Months Ended |       |
|---------------------|--------------------|-------|
|                     | March 31,          |       |
|                     | 2011               | 2010  |
| Cost of sales       | \$ 40              | \$ 98 |

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|                            |                 |                 |
|----------------------------|-----------------|-----------------|
| Sales and marketing        | 628             | 980             |
| General and administrative | 790             | 1,823           |
| Research and development   | 51              | 112             |
| <b>Total</b>               | <b>\$ 1,509</b> | <b>\$ 3,013</b> |

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

During the three months ended March 31, 2011 and 2010, there were 296,487 and 405,327 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's worldwide effective tax rate was (21%), representing a tax provision on a pre-tax loss and 33%, representing a tax provision on pre-tax income during the first quarters of 2011 and 2010, respectively. The principal factors affecting the Company's effective tax rate for the first quarter of 2011 are charges related to U.S. Government inquiries, for which the Company receives no tax benefit, the Company's mix of earnings among various tax jurisdictions state taxes, and current period losses in certain foreign jurisdictions for which the Company does not currently provide a tax benefit. The Company has not recorded 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 will be deductible for income tax purposes. A formal analysis of final settlement documents will be required to determine the nature and amount of the anticipated tax deductions if any. 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 inquiries for which no benefit was recorded. The effective tax rate of 33% for the first quarter of 2010 was affected by the gain on the sale of vascular operations and the mix of earnings among various tax jurisdictions. Excluding the sale of the Company's vascular operations, the Company's effective tax rate would have been approximately 38% for the first quarter of 2010.

As of March 31, 2011 and December 31, 2010, the Company's gross unrecognized tax benefit, inclusive of interest and penalties, was \$1.0 million. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within its global operations in income tax expense. As of March 31, 2011 and December 31, 2010, the Company had approximately \$0.4 million accrued for payment of interest and penalties. All of the unrecognized tax benefits would affect the Company's effective tax rate, if recognized. The Company does not anticipate that the amount of unrecognized tax benefits will change materially over the next twelve months.

The Company files a consolidated income tax return in the U.S. federal jurisdiction and numerous consolidated and separate income tax returns in many state and foreign jurisdictions. The statute of limitations with respect to federal tax authorities is closed for years prior to December 31, 2007. The statute of limitations for the various state tax filings is closed in most instances for years prior to December 31, 2006. 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 the Company's management reviews the financial information for operational decision making purposes. Beginning January 1, 2011, the Company began managing its business by its three GBUs, which are comprised of Spine, Orthopedics and Sports Medicine. These GBUs represent the current segments in which the Company's Chief Operating Decision Maker 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. Prior year disclosures have been revised to conform to these new GBU reporting segments. These new segments are discussed below.

*Spine*

Spine provides a portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of spinal conditions. This business unit specializes in the design, development and marketing of the Company's spine implant products along with bone growth stimulation and biologics products used in spine applications. Spine distributes its products through a network of distributors, sales representatives and affiliates. This business unit uses both direct and distributor sales representatives to sell spine products to hospitals, doctors, and other healthcare providers, primarily in the U.S.

**Table of Contents***Orthopedics*

Orthopedics provides a comprehensive portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to spine. This business unit specializes in the design, development and marketing of the Company's orthopedic implant products along with bone growth stimulation and biologics products used in orthopedic applications. Orthopedics distributes its products through a network of distributors, sales representatives and affiliates. This 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.

*Segment Information*

The table below presents external net sales by market sector:

| (US\$ in thousands)              | External Net Sales by Market Sector<br>Three Months Ended March 31, |                   |                    |                                |
|----------------------------------|---|-------------------|--------------------|--------------------------------|
|                                  | 2011  | 2010              | Reported<br>Growth | Constant<br>Currency<br>Growth |
| <b>Spine Products</b>            |   |                   |                    |                                |
| Stimulation                      | \$ 38,618   | \$ 41,930         | (8)%               | (8)%                           |
| Implants and Biologics           | 33,957  | 29,753            | 14%                | 14%                            |
| <b>Total Spine Products</b>      | <b>72,575</b>   | <b>71,683</b>     | <b>1%</b>          | <b>1%</b>                      |
| <b>Orthopedics Products</b>      | <b>40,473</b>   | <b>38,282</b>     | <b>6%</b>          | <b>4%</b>                      |
| Sports Medicine Products         | 24,743  | 23,602            | 5%                 | 5%                             |
| <b>Total Strategic Products</b>  | <b>137,791</b>  | <b>133,567</b>    | <b>3%</b>          | <b>3%</b>                      |
| Divested Products <sup>(1)</sup> | 1,374   | 5,256             | (74)%              | (74)%                          |
| <b>Total Net Sales</b>           | <b>\$ 139,165</b>   | <b>\$ 138,823</b> | <b>%</b>           | <b>%</b>                       |

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- (1) Divested Products sales for the three months ended March 31, 2011 and 2010 include \$1.4 million and \$3.1 million, respectively, related to the vascular business which was divested in March 2010 (see Note 16). This revenue represents amounts recognized in 2010 prior to the March 2010 sale date as well as revenue generated in the first quarter 2010 and 2011 from the transition services supply agreement that commenced upon the sale of the business. In addition, sales for the three months ended March 31, 2010 also include \$2.2 million related to the anesthesia product line. The Company exited its anesthesia product line after the expiration of its distribution agreement in the United Kingdom during the second quarter of 2010.

The tables below reconcile net sales by market sector to the Company's GBU reporting segments:

| (US\$ in thousands)      | Sales by GBU for the Three Months Ended March 31, 2011 |             |                 |            |
|--------------------------|--|-------------|-----------------|------------|
|                          | Spine  | Orthopedics | Sports Medicine | Total      |
| Spine Products           |  |             |                 |            |
| Stimulation              | \$ 38,618  | \$          | \$              | \$ 38,618  |
| Implants and Biologics   | 33,957   |             |                 | 33,957     |
| Total Spine Products     | 72,575   |             |                 | 72,575     |
| Orthopedics Products     |  | 40,473      |                 | 40,473     |
| Sports Medicine Products |  |             | 24,743          | 24,743     |
| Total Strategic Products | 72,575   | 40,473      | 24,743          | 137,791    |
| Divested Products        |  |             | 1,374           | 1,374      |
| Total Net Sales          | \$ 72,575  | \$ 40,473   | \$ 26,117       | \$ 139,165 |

| (US\$ in thousands)      | Sales by GBU for the Three Months Ended March 31, 2010 |             |                 |            |
|--------------------------|--|-------------|-----------------|------------|
|                          | Spine  | Orthopedics | Sports Medicine | Total      |
| Spine Products           |  |             |                 |            |
| Stimulation              | \$ 41,930  | \$          | \$              | \$ 41,930  |
| Implants and Biologics   | 29,753   |             |                 | 29,753     |
| Total Spine Products     | 71,683   |             |                 | 71,683     |
| Orthopedics Products     |  | 38,282      |                 | 38,282     |
| Sports Medicine Products |  |             | 23,602          | 23,602     |
| Total Strategic Products | 71,683   | 38,282      | 23,602          | 133,567    |
| Divested Products        |  | 2,187       | 3,069           | 5,256      |
| Total Net Sales          | \$ 71,683  | \$ 40,469   | \$ 26,671       | \$ 138,823 |

| (US\$ in thousands)            | Operating (Loss) Income by GBU |  | Three Months Ended |           |
|--------------------------------|--------------------------------|--|--------------------|-----------|
|                                |                                |  | March 31,          |           |
|                                |                                |  | 2011               | 2010      |
| Spine <sup>(1)</sup>           |                                |  | \$ (15,915)        | \$ 19,571 |
| Orthopedics <sup>(2)</sup>     |                                |  | (3,630)            | 3,338     |
| Sports Medicine <sup>(3)</sup> |                                |  | 1,327              | 14,404    |
| Corporate <sup>(4)</sup>       |                                |  | (7,843)            | (5,368)   |

|       |             |           |
|-------|-------------|-----------|
| Total | \$ (26,061) | \$ 31,945 |
|-------|-------------|-----------|



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- (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 inquiries and legal costs associated with those inquiries, respectively (see Note 18).
- (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 inquiries and legal costs associated with those inquiries, respectively (see Note 18).
- (3) For the three months ended March 31, 2010, the operating income for the Sports Medicine GBU included \$12.6 million from the gain on sale of vascular operations (see Note 16).
- (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 (see Note 18).

**15. Restructuring charges**

In the fourth quarter of 2010, the Company initiated a reorganization plan to further streamline operations and lower operating costs within its Spine, Orthopedics and Sports Medicine GBUs. During the year ended December 31, 2010, the Company recorded restructuring charges of \$0.4 million in Spine and \$3.2 million in Orthopedics which were related to employee severance costs. No further restructuring costs are anticipated. Employee severance payments will extend through the third quarter of 2011.

The following table presents changes in the restructuring liability, which is included within other current liabilities in the condensed consolidated balance sheets as of March 31, 2011 and December 31, 2010:

| (US\$ in thousands)          | Severance |
|------------------------------|-----------|
| Balance at December 31, 2010 | \$ 1,638  |
| Charges under 2010 plan      |           |
| Cash payments                | (1,173)   |
| Balance at March 31, 2011    | \$ 465    |

**16. Sale of vascular operations**

On March 8, 2010, the Company entered into an asset purchase agreement (the APA) in which the Company agreed to sell substantially all of its vascular operations related to the A-V IMPULSE SYSTEM® and related accessories (including finished products inventory and tangible assets). At the closing, the Company received payment of approximately \$27.7 million, which amount included the estimated value of certain finished products inventory conveyed at the closing and remains subject to post-closing verification.

Pursuant to the APA, the Company agreed to enter into certain transition arrangements at the closing, including (i) a transition services agreement pursuant to which, among other things, the Company agreed to continue to provide operational support with respect to the transferred assets in certain jurisdictions for a period of up to five months, and (ii) two separate supply agreements for certain ImPads for a period of two years and provide other products for a period of 90 days. During the second and third quarters of 2010, the Company completed the transition services agreement and one of the supply agreements (which supplies the other products). The Company also agreed to enter into a five-year noncompetition agreement at closing with respect to the business of the assets being transferred. Due to the continuing contractual involvement of these agreements, the transaction did not meet the criteria for presentation as discontinued operations.

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The following table presents the value of the asset disposition, proceeds received, net of litigation settlement costs and gain on sale of vascular operations as shown in the condensed consolidated statements of operations for the three months ended March 31, 2010.

| (US\$ in thousands)                               | Total     |
|---|-----------|
| Cash proceeds, net of litigation <sup>(1)</sup>   | \$ 24,193 |
| Less:   |           |
| Transaction related expenses                      | 1,699     |
| Inventory   | 1,570     |
| Tangible assets                                   | 799       |
| Identifiable intangible assets                    | 543       |
| Goodwill  | 7,031     |
| <br>  |           |
| Gain on sale of vascular operations               | 12,551    |
| Income tax expense                                | (3,498)   |
| <br>  |           |
| Gain on sale of vascular operations, net of taxes | \$ 9,053  |

- (1) In conjunction with the sale of the vascular operations, the Company settled an outstanding litigation claim by the former patent holders for \$3.5 million.

**17. Contingencies***Litigation*

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, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks 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 concerns 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's indemnification rights under the Blackstone Merger Agreement are described further below). The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has 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. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General'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. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General'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 U.S. Attorney's Office for the District of Massachusetts (the "Tolling Agreement" ) that extends 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.



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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 U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. 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 believes that this lawsuit is related to the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and the U.S. Attorney's Office for the District of Massachusetts, and the U.S. Department of Justice. The Company intends to defend vigorously against this lawsuit. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of the U.S. Department of Justice 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 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. The case is currently pending appeal at the United States Court of Appeals for the First Circuit.

On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the U.S. Attorney's Office for the District of Nevada ( USAO-Nevada subpoena ). The subpoena seeks documents for the period from January 1999 to the date of issuance of the subpoena. The Company believes that the subpoena concerns payments or gifts made by Blackstone to certain physicians. On February 29, 2008, Blackstone received a Civil Investigative Demand ( CID ) from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. The CID seeks documents for the period from March 2004 through the date of issuance of the CID, and the Company believes that the CID concerns Blackstone's financial relationships with certain physicians and related matters. The Ohio Attorney General's Office, Health Care Fraud Section has issued a criminal subpoena, dated August 8, 2008, to Orthofix Inc. (the Ohio AG subpoena ). The Ohio AG subpoena seeks documents for the period from January 1, 2000 through the date of issuance of the subpoena. The Company believes that the Ohio AG subpoena arises from a government investigation that concerns the compensation of physician consultants and related 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 the USAO-Nevada subpoena, the Massachusetts CID and the Ohio AG subpoena.

By order entered on January 4, 2007, the U.S. District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. The amended complaint in the Thomas action alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan and another provider. The Company believes that Blackstone has meritorious defenses to the claims alleged and the Company intends to defend vigorously against this lawsuit. On or about May 10, 2010 the Court granted the parties joint motion to stay all proceedings for six months, which stay has subsequently been extended indefinitely. On September 17, 2007, 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. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have 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 are 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 March 31, 2011 and December 31, 2010, the escrow fund, which has subsequently accrued interest, contained \$52 million. The Company is also entitled to seek direct personal recourse against certain principal shareholders of Blackstone after all monies on deposit in the escrow fund have been paid

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out or released or are the subject of pending or unresolved indemnification claims but only for a period of six years from the closing date of the merger and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

In addition to the foregoing claims, the Company has submitted claims for indemnification from the escrow fund for losses that have resulted or may result from certain civil actions filed against Blackstone as well as certain claims against Blackstone alleging rights to payments for Blackstone stock options not reflected in Blackstone's corporate ledger at the time of its acquisition by the Company, or that the shares or stock options subject to those claims were improperly diluted by Blackstone. To date, the representative of the former shareholders of Blackstone has not objected to approximately \$1.5 million in such claims from the escrow fund, with certain claims remaining pending.

Although the Company believes amounts submitted to the escrow fund, net of any reserve, represent valid claims and are realizable, the outcome of each of the escrow claims described above in the preceding paragraphs is difficult to predict. Consequently, any estimate of the amount that may ultimately be returned to the Company from the escrow fund is not certain and there can be no assurance that losses to the Company from these matters will not exceed the amount of the escrow fund. Expenses incurred by the Company relating to the above matters are recorded as an escrow receivable in the condensed consolidated financial statements to the extent the Company believes, among other things, that collection of the claims is reasonably assured. Expenditures related to such matters for which the Company believes collection is doubtful are recognized in earnings when incurred. As of March 31, 2011 and December 31, 2010, the escrow receivable was approximately \$15.2 million and \$14.9 million, respectively, related to the Blackstone matters described above. These amounts include, among other things, attorneys' fees and costs related to the government investigations manifested by the subpoenas described above, the stock option-related claims described above, and costs related to the qui tam actions described above. As described above, these reimbursement claims are generally being contested by the representative of the former shareholders of Blackstone. To mitigate the risk that some reimbursement claims will not be collected, the Company records a reserve against the escrow receivable during the period in which reimbursement claims are recognized.

Effective October 29, 2007, Blackstone entered into a settlement agreement of a patent infringement lawsuit brought by certain affiliates of Medtronic Sofamor Danek USA Inc. In that lawsuit, the Medtronic plaintiffs had alleged that they were the exclusive licensees of certain U.S. patents and that Blackstone was making, selling, offering for sale and using its Blackstone Anterior Cervical Plate, 3 Degree Anterior Cervical Plate, Hallmark Anterior Cervical Plate, Reliant Cervical Plate, Pillar PEEK and Construx Mini PEEK VBR System products within the U.S. willfully infringed the subject patents. Blackstone denied infringement and asserted that the patents were invalid. The settlement agreement is not expected to have a material impact on the consolidated financial position, results of operations or cash flows. On July 20, 2007, 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. The Company was subsequently notified by legal counsel of the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

On or about April 10, 2009, the Company received a HIPAA subpoena (HIPAA subpoena) issued by the U.S. Attorney's Office for the District of Massachusetts (the Boston USAO). The subpoena sought documents concerning, among other things, the promotion and marketing of the 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. Document production in response to the subpoenas is ongoing. 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 and intends to continue to cooperate with the government's requests. In meetings with the Company and its attorneys regarding this matter, the Boston USAO informed the Company that it is investigating possible criminal and civil violations of federal law related to the promotion and marketing of its bone growth stimulator devices.

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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 bone growth 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 court, 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 bone growth 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.

With respect to the matters related to the HIPAA subpoena and Bierman qui tam complaint, see Note 18.

On or about July 2, 2009, the Company obtained a copy of a qui tam complaint filed by Marcus Laughlin that is pending in the U.S. District Court for the District of Massachusetts against the Company. The complaint has been consolidated with the complaint described in the immediately preceding paragraph, and was unsealed on June 30, 2009. The Company was served with the complaint on or about September 9, 2009. With leave of Court, Relator filed a Second Amended Complaint on June 23, 2010 against the Company and against Orthofix Inc. The complaint alleges violations of the federal False Claims Act and various state and local false claims acts, fraudulent billing, illegal kickbacks, conspiracy and wrongful termination based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products and provided physicians kickbacks in the form of free units, referral fees and fitting fees. The complaint also alleges that TRICARE has been reimbursing the Company for its Cervical Stim<sup>®</sup> product without approval to do so. On or about November 4, 2010, the U.S. District Court for the District of Massachusetts granted in part and denied in part the Company's motion to dismiss. The Court dismissed all claims against Orthofix Inc., and dismissed all claims against the Company except for Laughlin's employment retaliation claim. The Court denied Laughlin's request to amend the complaint to attempt to re-assert the dismissed claims. Thereafter, the Company filed a motion for judgment on the pleadings with respect to the employment retaliation claim. On May 4, 2011 the Court denied the Company's request to enter judgment in our favor, but agreed that the complaint fails to satisfy the pleading requirements necessary to allege a retaliation claim against the Company. The Court allowed Laughlin until May 18, 2011 to file an amended complaint with respect to this wrongful termination claim, in order to attempt to cure these deficiencies.

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 intends to vigorously defend these cases. On or about August 2, 2010, Breg received a HIPAA subpoena issued by the U.S. Department of Justice, which the Company believes relates to this matter. The subpoena seeks documents from the Company and its subsidiaries for the period January 1, 2000 through the date of the subpoena. Document production in response to the subpoena is ongoing.

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.

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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 ( SEC ) and the United States Department of Justice ( DOJ ) to advise both agencies that an internal investigation is 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 is cooperating with the SEC and DOJ in connection with the subpoena. With respect to this matter, see Note 18 for update.

The Company cannot predict with certainty the outcome of any proceedings, settlement discussions with the government or claims made against the Company or its subsidiaries described in the preceding paragraphs and there can be no assurance that the ultimate resolution of any claim will not have a material adverse impact on the Company's consolidated financial position, results of operations or cash flows.

In addition to the foregoing, in the normal course of 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 estimable, the Company provides appropriate amounts in the accompanying financial statements.

**18. Subsequent Events**

Subsequent to March 31, 2011, the Company reached an agreement in principle with the Boston USAO to resolve criminal and civil matters related to the previously disclosed government investigations of its bone growth stimulation business (see Note 17). The Company is currently in discussions with the Boston USAO, and expects to initiate discussions with the Office of Inspector General ( OIG ) of the Department of Health and Human Services in the near term, as to the final terms of a potential resolution of this matter. Based on information currently available, the Company believes that it is probable that a settlement with the U.S. Government will be reached and will, among other things, include monetary payments and certain related costs and expenses of approximately \$43 million. The Company has therefore recorded a charge for this amount during the first quarter of 2011. The final settlement is subject to the negotiation and execution of definitive agreements with the Boston USAO, the DOJ, and the OIG of the United States Department of Health and Human Services.

The Company recorded a further charge of \$3 million to establish an accrual in connection with the potential fines and penalties related to possible FCPA violations that it voluntarily reported to the U.S. Government in June 2010 and concerning its former Mexican orthopedic distribution entity. The Company completed its Promeca Internal Investigation in April 2011 and anticipates commencing potential settlement discussions with the U.S. government regarding this matter in late May 2011. The Company's establishment of this accrual is based on the results of its own internal investigation and an analysis of recent and similar FCPA resolutions. Further, based on the information available at this time any additional loss related to this matter is not reasonably estimable. The Company will continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government; actual liability could be higher than the amount accrued.

There can be no assurance that the Company will enter into a consensual resolution of either of these two matters, or what the final terms of any such resolutions might be.

Although neither of these matters has concluded, the Company believes that the costs for which the charges have been recognized during the first quarter of 2011 are probable of being incurred and paid during 2011. The potential settlements represent recognizable subsequent events and, in accordance with U.S. GAAP, the Company recorded certain charges associated with the potential settlement costs. These amounts are included in the caption "Charges related to U.S. Government inquiries" in the Company's first quarter 2011 condensed consolidated statements of operations and in "Accrued charges related to U.S. Government inquiries" on the condensed consolidated balance sheets as of March 31, 2011. In May 2011, the Company obtained an amendment to the Credit Agreement to provide additional capacity under the various restrictive negative covenants for the payment by the Company of the costs and expenses associated with each of these settlements (see Note 7).

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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 our operations for the three months ended March 31, 2011 compared to our results of operations for the three months ended March 31, 2010. 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 for the fiscal year ended December 31, 2010.

#### **General Overview**

We are a diversified orthopedic products company offering a broad line of surgical and non-surgical products for the Spine, Orthopedics and Sports Medicine segments. 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 bone growth stimulation products used to enhance the success rate of spinal fusions and to treat non-union fractures, external and internal fixation devices used in fracture treatment, 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 a device for cold therapy, bone cement and devices for removal of bone cement used to fix artificial implants.

We believe the keys to reaching our financial goals for 2011 include:

The successful introduction and market launch of new products across our three global business units.

An enhancement to the coverage and quality of our distribution networks across all business units primarily in the U.S.

A decrease in operating expenses as a percentage of revenues as we continue to leverage our operating infrastructure against the increase in revenues noted above.

The successful navigation and potential resolution of our ongoing government investigation activities.

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 other 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 foreign currency denominated 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 are recorded in the accumulated other comprehensive income component of shareholders' equity. Transactional foreign currency gains and losses, including those generated from intercompany operations, are included in other expense, net on our condensed consolidated statements of operations and were \$1.0 million and \$0.2 million for the three months ended March 31, 2011 and 2010, respectively.

Our business is generally not seasonal in nature. 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. We do not consider the backlog of firm orders to be material. 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.





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Through December 31, 2010, we managed our operations as five reportable segments: Domestic, Spinal Implants and Biologics, Breg, International and Group. Beginning January 1, 2011, we began managing our business by our three global business units ( GBUs ), which are comprised of Spine, Orthopedics and Sports Medicine. These GBUs represent the current segments in which our Chief Operating Decision Maker 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. Prior year disclosures have been revised to conform to these new GBU reporting segments. These new segments are discussed below. Corporate activities not necessarily identifiable with the three GBUs are recorded as part of Corporate. We have designated Presidents (or GBU leaders) to lead the various segments:

### *Spine*

Spine provides a portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of spinal conditions. This business unit specializes in the design, development and marketing of our spine implant products along with bone growth stimulation and biologics products used in spine applications. Spine distributes its products through a network of distributors, sales representatives and affiliates. This business unit uses both direct and distributor sales representatives to sell spine products to hospitals, doctors and other healthcare providers, primarily in the U.S.

### *Orthopedics*

Orthopedics provides a comprehensive portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to spine. This business unit specializes in the design, development and marketing of our orthopedic implant products along with bone growth stimulation and biologics products used in orthopedic applications. Orthopedics distributes its products through a network of distributors, sales representatives and affiliates. This 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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The following table displays net sales by market sector for the three months ended March 31, 2011 and 2010. 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.

| (US\$ in thousands)              | External Net Sales by Market Sector<br>Three Months Ended March 31, |                   |                    |                                |
|----------------------------------|---|-------------------|--------------------|--------------------------------|
|                                  | 2011  | 2010              | Reported<br>Growth | Constant<br>Currency<br>Growth |
| <b>Spine Products</b>            |   |                   |                    |                                |
| Stimulation                      | \$ 38,618   | \$ 41,930         | (8)%               | (8)%                           |
| Implants and Biologics           | 33,957  | 29,753            | 14%                | 14%                            |
| <b>Total Spine Products</b>      | <b>72,575</b>   | <b>71,683</b>     | <b>1%</b>          | <b>1%</b>                      |
| <b>Orthopedics Products</b>      | <b>40,473</b>   | <b>38,282</b>     | <b>6%</b>          | <b>4%</b>                      |
| Sports Medicine Products         | 24,743  | 23,602            | 5%                 | 5%                             |
| <b>Total Strategic Products</b>  | <b>137,791</b>  | <b>133,567</b>    | <b>3%</b>          | <b>3%</b>                      |
| Divested Products <sup>(1)</sup> | 1,374   | 5,256             | (74)%              | (74)%                          |
| <b>Total Net Sales</b>           | <b>\$ 139,165</b>   | <b>\$ 138,823</b> | <b>%</b>           | <b>%</b>                       |

- (1) Divested Products sales for the three months ended March 31, 2011 and 2010 include \$1.4 million and \$3.1 million, respectively, related to the vascular business which we divested in March 2010. This revenue represents amounts recognized in 2010 prior to the March 2010 sale date as well as revenue generated in the first quarter 2010 and 2011 from the transition services supply agreement that commenced upon the sale of the business. In addition, sales for the three months ended March 31, 2010 also include \$2.2 million related to the anesthesia product line. We exited the anesthesia product line after the expiration of our distribution agreement in the United Kingdom during the second quarter of 2010.

The tables below reconcile net sales by market sector to our GBU reporting segments:

| (US\$ in thousands)             | Sales by GBU for the Three Months Ended March 31, 2011 |                  |                  |                   |
|---------------------------------|--|------------------|------------------|-------------------|
|                                 | Spine  | Orthopedics      | Sports Medicine  | Total             |
| <b>Spine Products</b>           |  |                  |                  |                   |
| Stimulation                     | \$ 38,618  | \$               | \$               | \$ 38,618         |
| Implants and Biologics          | 33,957   |                  |                  | 33,957            |
| <b>Total Spine Products</b>     | <b>72,575</b>  |                  |                  | <b>72,575</b>     |
| <b>Orthopedics Products</b>     |  | <b>40,473</b>    |                  | <b>40,473</b>     |
| Sports Medicine Products        |  |                  | 24,743           | 24,743            |
| <b>Total Strategic Products</b> | <b>72,575</b>  | <b>40,473</b>    | <b>24,743</b>    | <b>137,791</b>    |
| Divested Products               |  |                  | 1,374            | 1,374             |
| <b>Total Net Sales</b>          | <b>\$ 72,575</b>                                       | <b>\$ 40,473</b> | <b>\$ 26,117</b> | <b>\$ 139,165</b> |



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| (US\$ in thousands)      | Sales by GBU for the Three Months Ended March 31, 2010 |             |                 |            |
|--------------------------|--|-------------|-----------------|------------|
|                          | Spine  | Orthopedics | Sports Medicine | Total      |
| Spine Products           |  |             |                 |            |
| Stimulation              | \$ 41,930  | \$          | \$              | \$ 41,930  |
| Implants and Biologics   | 29,753   |             |                 | 29,753     |
| Total Spine Products     | 71,683   |             |                 | 71,683     |
| Orthopedics Products     |  | 38,282      |                 | 38,282     |
| Sports Medicine Products |  |             | 23,602          | 23,602     |
| Total Strategic Products | 71,683   | 38,282      | 23,602          | 133,567    |
| Divested Products        |  | 2,187       | 3,069           | 5,256      |
| Total Net Sales          | \$ 71,683  | \$ 40,469   | \$ 26,671       | \$ 138,823 |

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

|  | Three Months Ended<br>March 31, |             |
|--|---------------------------------|-------------|
|  | 2011<br>(%)                     | 2010<br>(%) |
| Net sales                                    | 100                             | 100         |
| Cost of sales                                | 24                              | 24          |
| Gross profit                                 | 76                              | 76          |
| Operating expenses:                          |                                 |             |
| Sales and marketing                          | 40                              | 41          |
| General and administrative                   | 17                              | 15          |
| Research and development                     | 4                               | 5           |
| Amortization of intangible assets            | 1                               | 1           |
| Gain on sale of vascular operations          |                                 | (9)         |
| Charges related to U.S. Government inquiries | 33                              |             |
| Operating (loss) income                      | (19)                            | 23          |
| Net (loss) income                            | (26)                            | 13          |

**Three Months Ended March 31, 2011 Compared to Three Months Ended March 31, 2010**

Net sales increased \$0.4 million to \$139.2 million in the first quarter of 2011 compared to \$138.8 million for the same period last year. The impact of foreign currency increased sales by \$0.5 million during the first quarter of 2011 when compared to the first quarter of 2010.

*Sales*

Net sales in our Spine GBU increased to \$72.6 million in the first quarter of 2011 compared to \$71.7 million for the same period last year, an increase of 1%. The increase in Spine's net sales was partially the result of a 29% increase in sales of our biologics products when compared to the same period in the prior year. In addition, sales in our thorocolumbar and interbody devices increased 17% and 8%, respectively, for the first quarter of 2011 compared to the same period in the prior year due to increased sales of our Firebird pedicle screw system and our Pillar SA interbody device. These sales increases were partially offset by a decrease of 8% in our spine stimulation products, respectively, in the first quarter of 2011 when compared to the same period in the prior year, primarily as a result of the ongoing industry wide investigation of the bone growth stimulation business and industry reimbursement challenges.

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Net sales in our Orthopedics GBU increased to \$40.5 million in the first quarter of 2011 compared to \$38.3 million for the same period last year, an increase of 6%. The impact of foreign currency increased Orthopedics' net sales by 1% or \$0.5 million, during the first quarter of 2011 as compared to the first quarter of 2010. This increase was led by our external fixation platform along with the increased use of Trinity® Evolution in orthopedic applications. Sales of our hardware products and biologics products increased 14% and 42%, respectively, during the first quarter of 2011 when compared with the same period last year. These sales increases were offset by a decrease in our Physio-Stim® product line.

Net sales in our Sports Medicine GBU increased to \$24.7 million in the first quarter of 2011 compared to \$23.6 million for the same period in the prior year, an increase of 5%. The increase in net sales was due to improved performances of our bracing product lines. The first quarter of 2011 also included revenue of \$0.5 million from a billing business that was acquired during the first quarter of 2011.

Net sales of our Divested Products for the three months ended March 31, 2011 and 2010 include \$1.4 million and \$3.1 million, respectively, related to the vascular business which we divested in March 2010. This revenue represents amounts recognized in 2010 prior to the March 2010 sale date as well as revenue generated in the first quarter 2010 and in the first quarter 2011 from the transition services supply agreement that commenced upon the sale of the business. In addition, sales for the three months ended March 31, 2010 also include \$2.2 million related to the anesthesia product line. We exited the anesthesia product line after the expiration of our distribution agreement in the United Kingdom during the second quarter of 2010.

*Gross Profit* Our gross profit decreased \$0.3 million to \$105.8 million in the first quarter of 2011, compared to \$106.1 million for the same period last year. Gross profit as a percent of net sales in the first quarter of 2011 was 76.0% compared to 76.4% for the same period last year. The gross profit in the first quarter of 2010 also includes the impact of a \$1.9 million increase in the provision for inventory obsolescence recorded in connection with the discontinued U.S. Advent Cervical disc clinical trial. Excluding the impact of this adjustment, gross profit as a percent of net sales in the first quarter of 2010 would have been 77.8%. This reduction in the adjusted gross profit margin is primarily a result of increased pricing pressures in the U.S. spine fusion and sports medicine markets along with an unfavorable 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 decreased \$0.7 million, or 1%, to \$55.6 million in the first quarter of 2011 compared to \$56.3 million in the first quarter of 2010. As a percent of net sales, sales and marketing expense was 40.0% and 40.5% in the first quarter of 2011 and 2010, respectively.

*General and Administrative Expense* General and administrative expense increased \$1.5 million, or 7%, in the first quarter of 2011 to \$23.0 million compared to \$21.5 million in the first quarter of 2010. General and administrative expense as a percent of net sales was 16.5% in the first quarter of 2011 compared to 15.5% for the same period last year. The increase in general and administrative expense relates to increased legal costs associated with ongoing 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. These expenses were partially offset by a reduction in stock-based compensation expenses of \$1.5 million in the three months ended March 31, 2011 when compared to the same period in the prior year and savings associated with our past restructuring activities.

*Research and Development Expense* Research and development expense decreased \$1.4 million in the first quarter of 2011 to \$6.1 million compared to \$7.5 million for the same period last year. As a percent of sales, research and development expense was 4.3% in the first quarter of 2011 compared to 5.4% for the same period last year. The decrease in research and development expenses in the first quarter of 2011 compared to the same period in the prior year was due to timing of spending related to our ongoing research, development and clinical activities.

*Amortization of Intangible Assets* Amortization of intangible assets decreased \$0.1 million in the first quarter of 2011 to \$1.3 million compared to \$1.4 million for the same period last year.

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*Gain on Sale of Vascular Operations* Gain on sale of vascular operations was \$12.6 million in the first quarter of 2010 and represented the gain on the sale of our vascular operations related to the A-V IMPULSE SYSTEM® and related accessories on March 8, 2010. No such gain was recorded in the first quarter of 2011.

*Charges Related to U.S. Government Inquiries* Subsequent to March 31, 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 bone growth stimulation business. Based on information currently available, we believe that it is probable that a settlement with the U.S. Government will be reached and will, among other things, include monetary payments and certain related costs and expenses of approximately \$43 million. We have therefore recorded a charge for this amount during the first quarter of 2011. There can be no assurance that we will enter into a consensual resolution of this matter with the Boston USAO or OIG, or what the terms of any such resolution might be.

We also recorded a further charge of \$3 million to establish an accrual in connection with the potential fines and penalties related to possible Foreign Corrupt Practices Act violations that we voluntarily reported to the U.S. Government in June 2010 concerning our former Mexican orthopedic distribution entity. We completed our Promeca Internal Investigation in April 2011 and anticipate commencing potential settlement discussions with the U.S. government regarding this matter in late May 2011. The establishment of this accrual is based on the results of our own internal investigation and an analysis of recent and similar FCPA resolutions. Further, based upon the information available at this time any additional loss related to this matter is not reasonably estimable. We will continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government; actual liability could be higher than the amount accrued.

Although neither of these matters has concluded, we believe that the costs for which the charges have been recognized during the first quarter are probable of being incurred and paid during 2011. We have recorded these charges associated with the potential settlement costs as Charges related to U.S. Government inquiries.

*Interest Expense, net* Interest expense, net was \$2.4 million for the first quarter of 2011 compared to \$5.8 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.

*Gain on Interest Rate Swap* In June 2008, we entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in our former credit facility, the Swap was no longer deemed highly effective. Special hedge accounting was no longer applied and fair value adjustments were reported in current earnings. On June 29, 2010, we settled the Swap with the financial institution holder of the derivative instrument. For the three months ended March 31, 2010, we recorded a gain of \$0.3 million related to the change in the fair value of the Swap. The Swap was settled on June 29, 2010.

*Other Expense, net* Other expense, net was \$1.1 million and \$0.3 million for the first quarter of 2011 and 2010, respectively. The increase 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 (21%), representing a tax provision on a pre-tax loss, and 33%, representing a tax provision on pre-tax income during the first quarters of 2011 and 2010, respectively. 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. We have not recorded 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 will be deductible for income tax purposes. A formal analysis of final settlement documents will be required to determine the nature and amount of the anticipated tax deductions if any. 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. The effective tax rate of 33% for the first quarter of 2010 was affected by the gain on the sale of vascular operations and the mix of earnings among various tax jurisdictions. Excluding the sale of our vascular operations, our effective tax rate would have been approximately 38% for the first quarter of 2010. We incur losses 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.

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*Net (Loss) Income* Net loss for the first quarter of 2011 was \$35.8 million, or (\$2.00) per basic and diluted share, compared to net income of \$17.5 million, or \$1.00 per basic and \$0.99 per diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,937,280 and 17,489,315 during the first quarters of 2011 and 2010, respectively. The weighted average number of diluted common shares outstanding was 17,937,280 and 17,757,099 during the first quarters of 2011 and 2010, respectively.

**Liquidity and Capital Resources**

Cash and cash equivalents at March 31, 2011 were \$48.8 million, of which \$25.4 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$36.5 million at December 31, 2010, of which \$22.9 million was subject to certain restrictions under the senior secured credit agreement discussed below.

Net cash provided by operating activities was \$18.8 million and \$3.9 million for the three months ended March 31, 2011 and 2010, respectively. Net cash provided by operating activities is comprised of net (loss) income, non-cash items (including depreciation and amortization, provision for doubtful accounts, provision for inventory obsolescence, share-based compensation, deferred income taxes and gain on sale of vascular operations) and changes in working capital. Net income decreased \$53.3 million to a net loss of (\$35.8) million for the three months ended March 31, 2011 from net income of \$17.5 million for the comparable period in the prior year. Non-cash items for the three months ended March 31, 2011 increased \$12.1 million to \$9.7 million compared to a decrease of \$2.4 million in the same period of 2010 primarily as a result of the net gain on the sale of vascular operations of \$12.6 million. Working capital accounts provided \$44.9 million of cash in the three months ended March 31, 2011 compared to \$11.1 million for the same period last year. The principal change in working capital can be mainly attributed to charges related to U.S. Government inquiries of \$46.0 million and an improved trade accounts receivable cash inflow of \$9.7 million, primarily the result of our Italian subsidiary factoring \$5.5 million of its trade accounts receivable to an outside agency during the first quarter of 2011. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 87 days at March 31, 2011 and March 31, 2010 and inventory turns of 1.4 times at March 31, 2011 compared to 1.5 times at March 31, 2010. Also included in cash used in working capital in 2011 were \$0.3 million in costs related to matters occurring at Blackstone prior to the acquisition and for which we are seeking reimbursement from the applicable escrow fund.

Net cash used in investing activities was \$10.9 million for the three months ended March 31, 2011 compared to net cash provided by investing activities of \$19.8 million for the three months ended March 31, 2010. During the first quarter of 2010, we sold our vascular operations with cash proceeds, net of litigation settlement costs, for \$24.2 million. 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, 2011 and 2010, we invested \$5.7 million and \$4.4 million in capital expenditures, respectively.

Net cash provided by financing activities was \$1.8 million for the three months ended March 31, 2011 compared to net cash used in financing activities of \$18.0 million for the three months ended March 31, 2010. During the three months ended March 31, 2011, we repaid approximately \$1.3 million against the principal on our senior secured term loan compared to \$19.8 million during the three months ended March 31, 2010. Our restricted cash balance usage decreased \$2.0 million to \$2.4 million compared to a usage of \$4.4 million for the same period in 2010. During the three months ended March 31, 2011 and 2010, we received proceeds of \$7.3 million and \$4.6 million, respectively, from the issuance of 296,487 shares and 405,327 shares, respectively, of our common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

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



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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, 2011 and December 31, 2010, we had \$97.5 million and \$98.8 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. 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.

As of March 31, 2011 and December 31, 2010, the entire Term Loan Facility of \$97.5 million and \$98.8 million, respectively, was at the LIBOR rate plus a margin of 3.00%. In addition, as of March 31, 2011 and December 31, 2010, \$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, 2011 and December 31, 2010 was 3.4%.

The Credit Agreement requires us and Orthofix Holdings to comply with leverage and fixed charge 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 that we were in compliance with the affirmative covenants at March 31, 2011. 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, which could permit acceleration of the debt payments under the facility.

In May 2011, we obtained an amendment to the Credit Agreement (the Amended Credit Agreement ) to provide additional capacity under the various restrictive negative covenants for the payment by us of the Specified Settlement Amounts (as defined in the Amended Credit Agreement) associated with each of the potential settlements. The amendment updates the definition of Consolidated EBITDA to exclude Specified Settlement Amounts of up to \$50 million in the aggregate. As a result of the Amended Credit Agreement, we continue to comply with the leverage and fixed charge coverage ratios and the covenants set forth in the Amended Credit Agreement. We believe that we were in compliance with these financial covenants as measured at March 31, 2011. As defined in the Amended Credit Agreement, our leverage ratio cannot exceed 3.25 and our fixed charge ratio must be greater than or equal to 1.25. At March 31, 2011, our leverage and fixed charge ratios were 2.40 and 2.96, respectively.

As defined in the Amended Credit Agreement, the leverage ratio we cannot exceed is 3.25 for the life of the agreement and the fixed charge coverage ratio must be greater or equal to 1.25 for the life of the agreement. Based on our projected earnings, we believe that we should be able to meet these financial covenants in future fiscal quarters; however, there can be no assurance that we will be able to do so, and failure to do so could result in an event of default under the credit agreement, which could have a material adverse effect on our financial position.

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, debt repayments, and payment of Specified Settlement Amounts. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of March 31, 2011 and December 31, 2010 was \$191.7 million and \$178.5 million, respectively. In addition, the Credit Agreement restricts us and our subsidiaries that are not parties to the Credit Facilities from access to cash held by Orthofix Holdings and its subsidiaries. The amount of our restricted cash as of March 31, 2011 and December 31, 2010 was \$25.4 million and \$22.9 million, respectively.

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In conjunction with obtaining the Credit Facilities, we incurred debt issuance costs of \$4.3 million which are being amortized using the effective interest method over the life of the Credit Facilities. As of March 31, 2011 and December 31, 2010, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were \$3.7 million and \$3.9 million, respectively.

At March 31, 2011, we had outstanding borrowings of 1.4 million (\$2.0 million) and unused available lines of credit of approximately 5.9 million (\$8.3 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line 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 line 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 and research and development projects formerly mentioned, over the near term.

In the fourth quarter of 2010, we initiated a reorganization plan to further streamline operations and lower operating costs within our Spine, Orthopedics and Sports Medicine GBUs. During the year ended December 31, 2010, we recorded restructuring charges of \$0.4 million in Spine and \$3.2 million in Orthopedics which were related to employee severance costs. No further restructuring costs are anticipated. Employee severance payments will extend through the third quarter of 2011.

The following table presents changes in the restructuring liability, which is included within other current liabilities in the condensed consolidated balance sheets as of March 31, 2011 and December 31, 2010:

| <b>(US\$ in thousands)</b>   | <b>Severance</b> |
|------------------------------|------------------|
| Balance at December 31, 2010 | \$ 1,638         |
| Charges under 2010 plan      |                  |
| Cash payments                | (1,173)          |
| Balance at March 31, 2011    | \$ 465           |

On March 8, 2010, we entered into an asset purchase agreement (the APA) in which we agreed to sell substantially all of our vascular operations related to the A-V IMPULSE SYSTEM® and related accessories (including finished products inventory and tangible assets). At the closing, we received payment of approximately \$27.7 million, which amount included the estimated value of certain finished products inventory conveyed at the closing and remains subject to post-closing verification.

Pursuant to the APA, we agreed to enter into certain transition arrangements at the closing, including (i) a transition services agreement pursuant to which, among other things, we agreed to continue to provide operational support with respect to the transferred assets in certain jurisdictions for a period of up to five months, and (ii) two separate supply agreements for certain ImPads for a period of two years and provide other products for a period of 90 days. During the second and third quarters of 2010, we completed the transition services agreement and one of the supply agreements (which supplies the other products). We also agreed to enter into a five-year noncompetition agreement at closing with respect to the business of the assets being transferred. Due to the continuing contractual involvement of these agreements, the transaction did not meet the criteria for presentation as discontinued operations.

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The following table presents the value of the asset disposition, proceeds received, net of litigation settlement costs and gain on sale of vascular operations as shown in the condensed consolidated statements of operations for the three months ended March 31, 2010.

| (US\$ in thousands)                               | Total     |
|---|-----------|
| Cash proceeds, net of litigation <sup>(1)</sup>   | \$ 24,193 |
| Less:   |           |
| Transaction related expenses                      | 1,699     |
| Inventory   | 1,570     |
| Tangible assets                                   | 799       |
| Identifiable intangible assets                    | 543       |
| Goodwill  | 7,031     |
| <br>  |           |
| Gain on sale of vascular operations               | 12,551    |
| Income tax expense                                | (3,498)   |
| <br>  |           |
| Gain on sale of vascular operations, net of taxes | \$ 9,053  |

(1) In conjunction with the sale of the vascular operations, we settled an outstanding litigation claim by the former patent holders for \$3.5 million.

Subsequent to March 31, 2011, we reached an agreement in principle with the Boston USAO to resolve criminal and civil matters related to the previously disclosed government investigations of its bone growth stimulation business (see Note 17). We are currently in discussions with the Boston USAO, and expect to initiate discussions with the Office of Inspector General (OIG) of the Department of Health and Human Services in the near term, as to the final terms of a potential resolution of this matter. Based on information currently available, we believe that it is probable that a settlement with the U.S. Government will be reached and will, among other things, include monetary payments and certain related costs and expenses of approximately \$43 million. We have therefore recorded a charge for this amount during the first quarter of 2011. The final settlement is subject to the negotiation and execution of definitive agreements with the Boston USAO, the DOJ, and the OIG of the United States Department of Health and Human Services.

We recorded a further charge of \$3 million to establish an accrual in connection with the potential fines and penalties related to possible FCPA violations that we voluntarily reported to the U.S. Government in June 2010 and concerning our former Mexican orthopedic distribution entity. We completed our Promeca Internal Investigation in April 2011 and anticipate commencing potential settlement discussions with the U.S. government regarding this matter in late May 2011. The establishment of this accrual is based on the results of our own internal investigation and an analysis of recent and similar FCPA resolutions. Further, based upon the information available at this time any additional loss related to this matter is not reasonably estimable. We will continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government; actual liability could be higher than the amount accrued.

There can be no assurance that we will enter into a consensual resolution of either of these two matters, or what the final terms of any such resolutions might be.

Although neither of these matters has concluded, we believe that the costs for which the charges have been recognized during the first quarter of 2011 are probable of being incurred and paid during 2011. The potential settlements represent recognizable subsequent events and, in accordance with U.S. GAAP, we recorded certain charges associated with the potential settlement costs. These amounts are included in the caption "Charges related to U.S. Government inquiries" in our first quarter 2011 condensed consolidated statements of operations and in "Accrued charges related to U.S. Government inquiries" on the balance sheet as of March 31, 2011. In May 2011, we obtained an amendment to the Credit Agreement to provide additional capacity under the various restrictive negative covenants for the payment by us of the costs and expenses associated with each of these settlements. It is our intention to fund as much of the payment with cash-on-hand when the payments are due and draw any additional amounts from our revolving credit facility.

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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, 2011, we had a currency swap in place to minimize foreign currency exchange risk related to a 38.3 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, 2011, the entire Term Loan Facility of \$97.5 million is at the LIBOR rate plus a margin of 3.00%. As of March 31, 2011, \$100.0 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00% and the remaining \$17.4 million of the Revolving Credit Facility is at a base (as defined in the Credit Agreement) 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, 2011, our effective interest rate on our Credit Facilities was 3.4%. Based on the balance outstanding under the Credit Facilities as of March 31, 2011, 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 \$2.1 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, 2011, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million (\$32.9 million). We recorded a foreign currency gain during the three months ended March 31, 2011 of \$2.0 million related to this un-hedged long-term intercompany balance in accumulated other comprehensive income, which resulted from the strengthening of the Euro against the U.S. dollar during the period. For the three months ended March 31, 2011, we recorded a foreign currency loss of \$1.0 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 from the beginning of the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the three months ended March 31, 2011 and 2010 by foreign currency exchange rate fluctuations with the weakening of the U.S. dollar against the local foreign currency during this 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 Chief Financial Officer and Senior Vice President of Finance, 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 Chief Financial Officer and Senior Vice President of Finance 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, 2011 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**

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, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks 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 concerns 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. (Our indemnification rights under the Blackstone Merger Agreement are described further below). We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has 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. The subpoena seeks documents from us for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerns the compensation of physician consultants and related matters, and further believe that it is associated with the Department of Health and Human Services, Office of Inspector General'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. The subpoena seeks documents from us for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerns the compensation of physician consultants and related matters, and further believe that it is associated with the Department of Health and Human Services, Office of Inspector General'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 U.S. Attorney's Office for the District of Massachusetts (the Tolling Agreement ) that extends 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 Blackstone and us 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 U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. 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 believe that this lawsuit is related to the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and the U.S. Attorney's Office for the District of Massachusetts, and the U.S. Department of Justice. We intend to defend vigorously against this lawsuit. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of the U.S. Department of Justice 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 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. The case is currently pending appeal at the United States Court of Appeals for the First Circuit.

On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the U.S. Attorney's Office for the District of Nevada ( USAO-Nevada subpoena ). The subpoena seeks documents for the period from January 1999 to the date of issuance of the subpoena. We believe that the subpoena concerns payments or gifts made by Blackstone to certain physicians. On February 29, 2008, Blackstone received a Civil Investigative

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Demand ( CID ) from the Massachusetts Attorney General s Office, Public Protection and Advocacy Bureau, Healthcare Division. The CID seeks documents for the period from March 2004 through the date of issuance of the CID, and we believe that the CID concerns Blackstone s financial relationships with certain physicians and related matters. The Ohio Attorney General s Office, Health Care Fraud Section has issued a criminal subpoena, dated August 8, 2008, to Orthofix Inc. (the Ohio AG subpoena ). The Ohio AG subpoena seeks documents for the period from January 1, 2000 through the date of issuance of the subpoena. We believe that the Ohio AG subpoena arises from a government investigation that concerns the compensation of physician consultants and related 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 the USAO-Nevada subpoena, the Massachusetts CID and the Ohio AG subpoena.

By order entered on January 4, 2007, the U.S. District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. The amended complaint in the Thomas action alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan and another provider. We believe that Blackstone has meritorious defenses to the claims alleged and we intend to defend vigorously against this lawsuit. On or about May 10, 2010 the Court granted the parties joint motion to stay all proceedings for six months, which stay has subsequently been extended indefinitely. On September 17, 2007, 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. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have 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 are 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 March 31, 2011, the escrow fund, which has subsequently accrued interest, contained \$52 million. We are also entitled to seek direct personal recourse against certain principal shareholders of Blackstone after all monies on deposit in the escrow fund have been paid out or released or are the subject of pending or unresolved indemnification claims but only for a period of six years from the closing date of the merger and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

In addition to the foregoing claims, we have submitted claims for indemnification from the escrow fund for losses that have resulted or may result from certain civil actions filed against Blackstone as well as certain claims against Blackstone alleging rights to payments for Blackstone stock options not reflected in Blackstone s corporate ledger at the time of its acquisition by us, or that the shares or stock options subject to those claims were improperly diluted by Blackstone. To date, the representative of the former shareholders of Blackstone has not objected to approximately \$1.5 million in such claims from the escrow fund, with certain claims remaining pending.

Although we believe amounts submitted to the escrow fund, net of any reserve, represent valid claims and are realizable, the outcome of each of the escrow claims described above in the preceding paragraphs is difficult to predict. Consequently, any estimate of the amount that may ultimately be returned to us from the escrow fund is not certain and there can be no assurance that losses to us from these matters will not exceed the amount of the escrow fund. Expenses incurred by us relating to the above matters are recorded as an escrow receivable in our condensed consolidated financial statements to the extent we believe, among other things, that collection of the claims is reasonably assured. Expenditures related to such matters for which we believe collection is doubtful are recognized in earnings when incurred. As of March 31, 2011 and December 31, 2010, the escrow receivable was approximately \$15.2 million and \$14.9 million, respectively, related to the Blackstone matters described above. These amounts include, among other things, attorneys fees and costs related to the government investigations manifested by the subpoenas described above, the stock option-related claims described above, and costs related to the qui tam actions described above. As described above, these reimbursement claims are generally being contested by the representative of the former shareholders of Blackstone. To mitigate the risk that some reimbursement claims will not be collected, we record a reserve against the escrow receivable during the period in which reimbursement claims are recognized.

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Effective October 29, 2007, Blackstone entered into a settlement agreement of a patent infringement lawsuit brought by certain affiliates of Medtronic Sofamor Danek USA Inc. In that lawsuit, the Medtronic plaintiffs had alleged that they were the exclusive licensees of certain U.S. patents and that Blackstone's making, selling, offering for sale and using its Blackstone Anterior Cervical Plate, 3 Degree Anterior Cervical Plate, Hallmark Anterior Cervical Plate, Reliant Cervical Plate, Pillar PEEK and Construx Mini PEEK VBR System products within the U.S. willfully infringed the subject patents. Blackstone denied infringement and asserted that the patents were invalid. The settlement agreement is not expected to have a material impact on our consolidated financial position, results of operations or cash flows. On July 20, 2007, 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. We were subsequently notified by legal counsel of the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

On or about April 10, 2009, we received a HIPAA subpoena ( HIPAA subpoena ) issued by the U.S. Attorney's Office for the District of Massachusetts (the Boston USAO ). The subpoena sought documents concerning, among other things, our promotion and marketing of 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. Document production in response to the subpoenas is ongoing. 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, and intend to continue to cooperate with the government's requests. In meetings with us and our attorneys regarding this matter, the Boston USAO informed us that it is investigating possible criminal and civil violations of federal law related to our promotion and marketing of our bone growth stimulator devices.

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 us, Orthofix Inc. and other companies that have allegedly manufactured bone growth 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 court, 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 bone growth 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.

In April 2011, we reached an agreement in principle with the Boston USAO to resolve the criminal and civil matters described in the immediately preceding two paragraphs. We are currently in discussions with the Boston USAO, and expect to initiate discussions with the Office of Inspector General ( OIG ) of the Department of Health and Human Services in the near term, as to the final terms of a potential resolution of these matters. Based on information currently available, we believe that it is probable that a settlement with the U.S. government will be reached and will, among other things, include monetary payments and certain related costs and expenses of approximately \$43 million. We have therefore recognized a contingent liability for this amount during the first quarter of 2011. However, 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.



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On or about July 2, 2009, we obtained a copy of a qui tam complaint filed by Marcus Laughlin that is pending in the U.S. District Court for the District of Massachusetts against us. The complaint has been consolidated with the complaint described in the Bierman qui tam matter described above, and was unsealed on June 30, 2009. We were served with the complaint on or about September 9, 2009. With leave of Court, Relator filed a Second Amended Complaint on June 23, 2010 against us and against Orthofix Inc. The complaint alleges violations of the federal False Claims Act and various state and local false claims acts, fraudulent billing, illegal kickbacks, conspiracy and wrongful termination based on allegations that we promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products and provided physicians kickbacks in the form of free units, referral fees and fitting fees. The complaint also alleges that TRICARE has been reimbursing us for our Cervical Stim<sup>®</sup> product without approval to do so. On or about November 4, 2010, the U.S. District Court for the District of Massachusetts granted in part and denied in part our motion to dismiss. The Court dismissed all claims against Orthofix Inc., and dismissed all claims against us except for Laughlin's employment retaliation claim. The Court denied Laughlin's request to amend the complaint to attempt to re-assert the dismissed claims. Thereafter, we filed a motion for judgment on the pleadings with respect to the employment retaliation claim. On May 4, 2011 the Court denied our request to enter judgment in our favor, but agreed that the complaint fails to satisfy the pleading requirements necessary to allege a retaliation claim against us. The Court allowed Laughlin until May 18, 2011 to file an amended complaint with respect to this wrongful termination claim, in order to attempt to cure these deficiencies.

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 intends to vigorously defend these cases. On or about August 2, 2010, Breg received a HIPAA subpoena issued by the U.S. Department of Justice, which we believe relates to this matter. The subpoena seeks documents from us and our subsidiaries for the period January 1, 2000 through the date of the subpoena. Document production in response to the subpoena is ongoing.

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.

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 SEC and the United States Department of Justice ( DOJ ) to advise both agencies that an internal investigation is 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 are cooperating with the SEC and DOJ in connection with the subpoena.

We completed the Promeca Internal Investigation in April 2011 and anticipate commencing settlement discussions with the U.S. government regarding this matter in late May 2011. We have established a \$3 million accrual in connection with a potential settlement. We will continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government; actual liability could be higher than the amount accrued. However, there can be no assurance that the Company will enter into a consensual resolution of this matter, or what the final terms of any such resolution might be.

We cannot predict with certainty the outcome of any proceedings, settlement discussions with the government or claims made against us or our subsidiaries described in the preceding paragraphs and there can be no assurance that the ultimate resolution of any claim will not have a material adverse impact on our consolidated financial position, results of operations, or cash flows.

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In addition to the foregoing, 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 estimable, we provide appropriate amounts in the accompanying financial statements.

**Item 1A. Risk Factors**

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

**We have reached an agreement in principle with the U.S. Attorney's Office for the District of Massachusetts to resolve criminal and civil matters related to an investigation of our bone growth stimulation business, and have taken a charge of approximately \$43 million. However, there can be no assurance that we will be able to reach a final resolution of this matter on these terms or otherwise.**

We recently reached an agreement in principle with the U.S. Attorney's Office for the District of Massachusetts (the Boston USAO) to resolve criminal and civil matters related to the previously disclosed government investigations of our bone growth stimulation business. We are currently in discussions with the Boston USAO, and expect to initiate discussions with the Office of Inspector General (OIG) of the Department of Health and Human Services in the near term, as to the final terms of a potential resolution of these matters. Based on information currently available, we believe that it is probable that a settlement with the U.S. government will be reached and we have recorded a charge of approximately \$43 million related to this matter during the first quarter of 2011. However, there can be no assurance that we will be able to enter into a consensual resolution of these matters on these or other terms.

The failure to settle these matters on these terms or otherwise could adversely affect our business and operations. In addition, a final settlement of these matters could impose other regulatory or contractual restrictions on our business. If we are unable to comply with any such restrictions, or otherwise fail to meet the terms of any settlement, it could adversely affect our business and operations.

**We recently completed investigating allegations of improper payments by local employees of one of our subsidiaries in Mexico and anticipate commencing settlement discussions with the U.S. government regarding this matter in late May 2011. We have established a \$3 million accrual in connection with a potential settlement, but there can be no assurance that we will be able to settle this matter, whether for this amount or otherwise.**

We recently completed the previously disclosed investigation into allegations of improper payments by employees of our Promeca S.A. de C.V. Mexican subsidiary in potential Foreign Corrupt Practices Act violations. We anticipate commencing settlement discussions with the U.S. government regarding this matter in late May 2011. We have established a \$3 million accrual in connection with a potential settlement, and intend to continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government. However, there can be no assurance that we will be able to enter into a consensual resolution of this matter, or what the final terms of any such resolution might be. In addition, a final settlement of this matter could impose other regulatory or contractual restrictions on our business. If we are unable to comply with any such restrictions, or otherwise fail to meet the terms of any settlement, it could adversely affect our business and operations.

**Our subsidiary, Orthofix Holdings, Inc.'s senior secured bank credit facility contains significant financial and operating restrictions, including financial covenants that we may be unable to satisfy in the future.**

When we acquired Blackstone on September 22, 2006, one of our wholly owned subsidiaries, Orthofix Holdings, Inc. (Orthofix Holdings), entered into a senior secured bank credit facility with a syndicate of financial institutions to finance the transaction. On August 30, 2010, we entered into a new senior secured bank credit facility with a new syndicate of financial institutions, and used these borrowings to repay all amounts owed under the 2006 facility. We and certain of Orthofix Holdings' direct and indirect subsidiaries, including Orthofix Inc., Breg, and Blackstone have guaranteed the obligations of Orthofix Holdings under the new senior secured bank facility. The

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new senior secured bank facility provides for (1) a five-year term loan facility of \$100 million, of which \$97.5 million was outstanding at March 31, 2011, and (2) a five-year revolving credit facility of \$200 million upon which we had \$117.4 million outstanding and \$82.6 million available to be drawn as of March 31, 2011. 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 are due quarterly.

We believe we were in compliance with the affirmative covenants at March 31, 2011. In May 2011, we obtained an amendment to the Credit Agreement (the Amended Credit Agreement ) to provide additional capacity under the various restrictive negative covenants for the payment by us of the Specified Settlement Amounts (as defined in the Amended Credit Agreement) associated with each of the potential settlements (see Note 18).

The credit agreement contains negative covenants applicable to us and our subsidiaries, including restrictions on indebtedness, liens, dividends and mergers and sales of assets. The credit agreement also contains certain financial covenants, including a fixed charge coverage ratio and a leverage ratio applicable to us and our subsidiaries on a consolidated basis. A breach of any of these covenants could result in an event of default under the credit agreement, which could permit acceleration of the debt payments under the facility. As a result of the Amended Credit Agreement, we believe that we were in compliance with the negative covenants at March 31, 2011 and there were no events of default. Further, we believe that we should be able to meet these financial covenants in future fiscal quarters, however, there can be no assurance that we will be able to do so, and failure to do so could result in an event of default under the credit agreement, which could have a material adverse effect on our financial position.

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**Item 6. Exhibits**

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| 2.1                       | Agreement and Plan of Merger, dated as of August 4, 2006, among Orthofix International N.V., Orthofix Holdings, Inc., New Era Medical Limited, Blackstone Medical, Inc. and William G. Lyons, III, as Equityholders Representative (filed as an exhibit to the Company's current report on Form 8-K filed August 7, 2006 and incorporated herein by reference).   |
| 2.2                       | Asset Purchase Agreement, dated as of March 8, 2010, by and between Tyco Healthcare Group LP d/b/a Covidien, Covidien AG, Mallinckrodt do Brasil Ltda, Kendall de Mexico S.A. de C.V., Novamedix Limited, Novamedix Distribution Limited, Novamedix Services Limited, Promeca S.A. de C.V., Orthofix do Brasil, Orthofix S.r.l., Orthofix S.A., Intavent Orthofix 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). |
| 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 quarterly report on Form 10-Q for the quarter ended June 30, 2008 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*                     | Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended.   |
| 10.6                      | 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).   |
| 10.7                      | 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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- 10.8 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).
- 10.9 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).
- 10.10 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).
- 10.11 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).
- 10.12 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).
- 10.13 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).
- 10.14 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).
- 10.15 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).
- 10.16 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).
- 10.17 Inducement Stock Option Agreement between Orthofix International N.V. and Kevin L. Unger, dated August 17, 2009 (filed as an exhibit to the Company's current report on Form 8-K filed August 17, 2009 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.

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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.  |
| 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  | Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).                      |
| 10.27  | Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).    |
| 10.28  | 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).                   |
| 10.29  | 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). |

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- 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).
- 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 Amended and Restated Employment Agreement, entered into on November 16, 2009, 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, 2009 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.
- 10.37 Amended and Restated Employment Agreement, entered into on September 4, 2009, by and between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company's current report on Form 8-K filed September 11, 2009 and incorporated 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).
- 10.40 Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
- 10.41 Letter Agreement, dated July 25, 2009, between Orthofix Inc. and Raymond C. Kolls (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).
- 10.42 Letter Agreement, dated January 29, 2010, between Orthofix Inc. and Raymond C. Kolls (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).

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- 10.43 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Bradley R. Mason (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.44 Amendment No. 1 to Amended and Restated Employment Agreement, dated July 31, 2009, by and between Orthofix Inc. and Bradley R. Mason (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).
- 10.45 Amended and Restated Employment Agreement, entered into on October 23, 2009 and effective as of November 1, 2009, by and between Orthofix Inc. and Bradley R. Mason (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).
- 10.46 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).
- 10.47 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).
- 10.48 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.

\* 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.

Date: May 10, 2011

By: /s/ Alan W. Milinazzo  
Name: Alan W. Milinazzo  
Title: Chief Executive Officer and President

Date: May 10, 2011

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