

ORTHOFIX INTERNATIONAL N V
Form 10-Q
July 31, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2009

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)

Netherlands Antilles
(State or other jurisdiction of incorporation or organization)

N/A
(I.R.S. Employer Identification No.)

7 Abraham de Veerstraat
Curaçao
Netherlands Antilles
(Address of principal executive offices)

N/A
(Zip Code)

599-9-4658525
(Registrant's telephone number, including area code)

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

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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, or a non-accelerated filer. See definition of “accelerated filer and large accelerated filer” in Rule 12b-2 of the Exchange Act. (Check one): Large Accelerated filer Accelerated filer Non-Accelerated filer

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 July 29, 2009, 17,171,318 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, which relate to our business and financial outlook and 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,” “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 to reflect new information, the occurrence of future events or circumstances or otherwise.

Factors that could cause actual results to differ materially from those indicated by the forward-looking statements or that could contribute to such differences include, but are not limited to, risks relating to the expected sales of products, including recently launched products, unanticipated expenditures, changing relationships with customers, suppliers, strategic partners and lenders, unfavorable results in litigation matters, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, changes to and interpretation of governmental regulation of medical devices, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry and the economy, currency or interest rate fluctuations, corporate development and marketing development activities, including acquisitions and divestitures, unexpected costs or operating unit performance related to recent acquisitions, unexpected difficulties meeting covenants under our senior secured bank credit facility and the other risks described under Item 1A – “Business – Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and Part II, Item 1A – “Risk Factors” in this Form 10-Q.

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PART I FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

CONDENSED CONSOLIDATED BALANCE SHEETS

(US Dollars, in thousands except share data)

| | June 30, 2009 (unaudited) | December 31, 2008 |
|--|---------------------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$5,918 | \$ 14,594 |
| Restricted cash | 15,617 | 10,998 |
| Trade accounts receivable, less allowance for doubtful accounts of \$7,141 and \$6,473 at June 30, 2009 and December 31, 2008, respectively | 119,714 | 110,720 |
| Inventories, net | 94,172 | 91,185 |
| Deferred income taxes | 19,571 | 17,543 |
| Prepaid expenses and other current assets | 32,075 | 29,610 |
| Total current assets | 287,067 | 274,650 |
| Investments, at cost | 2,095 | 2,095 |
| Property, plant and equipment, net | 34,226 | 32,660 |
| Patents and other intangible assets, net | 50,893 | 53,546 |
| Goodwill | 185,270 | 182,581 |
| Deferred taxes and other long-term assets | 12,235 | 15,683 |
| Total assets | \$571,786 | \$ 561,215 |
| Liabilities and shareholders' equity | | |
| Current liabilities: | | |
| Bank borrowings | \$3,080 | \$ 1,907 |
| Current portion of long-term debt | 3,333 | 3,329 |
| Trade accounts payable | 23,749 | 23,865 |
| Other current liabilities | 54,442 | 45,894 |
| Total current liabilities | 84,604 | 74,995 |
| Long-term debt | 260,910 | 277,533 |
| Deferred income taxes | 3,940 | 4,509 |
| Other long-term liabilities | 4,680 | 2,117 |
| Total liabilities | 354,134 | 359,154 |
| Contingencies (Note 19) | | |
| Shareholders' equity: | | |
| Common shares \$0.10 par value; 50,000,000 shares authorized; 17,129,619 and 17,103,142 issued and outstanding as of June 30, 2009 and December 31, 2008, respectively | 1,713 | 1,710 |
| Additional paid-in capital | 171,947 | 167,818 |
| Retained earnings | 38,470 | 29,647 |
| Accumulated other comprehensive income | 5,522 | 2,886 |
| Total shareholders' equity | 217,652 | 202,061 |
| Total liabilities and shareholders' equity | \$571,786 | \$ 561,215 |

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

Table of ContentsCONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2009 AND 2008(Unaudited, US Dollars, in thousands except share and
per share data)

| | Three Months Ended | | Six Months Ended | |
|--|--------------------|------------|------------------|------------|
| | 2009 | 2008 | 2009 | 2008 |
| Net sales | \$ 137,546 | \$ 130,039 | \$ 266,520 | \$ 258,071 |
| Cost of sales | 36,909 | 35,048 | 69,715 | 69,286 |
| Gross profit | 100,637 | 94,991 | 196,805 | 188,785 |
| Operating expenses | | | | |
| Sales and marketing | 55,272 | 53,246 | 107,536 | 103,442 |
| General and administrative | 21,191 | 18,779 | 43,875 | 40,959 |
| Research and development | 8,886 | 6,599 | 17,973 | 12,953 |
| Amortization of intangible assets | 1,643 | 4,830 | 3,276 | 9,873 |
| Gain on sale of Pain Care® operations | - | - | - | (1,570) |
| | 86,992 | 83,454 | 172,660 | 165,657 |
| Operating income | 13,645 | 11,537 | 24,145 | 23,128 |
| Other income (expense), net | | | | |
| Interest expense, net | (5,831) | (4,069) | (11,948) | (9,459) |
| Unrealized non-cash gain on interest rate swap | 1,036 | - | 1,275 | - |
| Other income | 425 | 591 | 102 | 1,085 |
| | (4,370) | (3,478) | (10,571) | (8,374) |
| Income before income taxes | 9,275 | 8,059 | 13,574 | 14,754 |
| Income tax expense | (3,331) | (2,251) | (4,751) | (5,340) |
| Net income | \$ 5,944 | \$ 5,808 | \$ 8,823 | \$ 9,414 |
| Net income per common share - basic | \$ 0.35 | \$ 0.34 | \$ 0.52 | \$ 0.55 |
| Net income per common share - diluted | \$ 0.35 | \$ 0.34 | \$ 0.51 | \$ 0.55 |
| Weighted average number of common shares - basic | 17,107,084 | 17,090,217 | 17,105,323 | 17,088,735 |
| Weighted average number of common shares - diluted | 17,172,557 | 17,116,015 | 17,139,789 | 17,240,004 |

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

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FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

| (Unaudited, US Dollars, in thousands) | 2009 | 2008 |
|---|-----------|-----------|
| Cash flows from operating activities: | | |
| Net income | \$8,823 | \$9,414 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 10,614 | 14,777 |
| Amortization of debt costs | 99 | 632 |
| Provision for doubtful accounts | 3,487 | 3,019 |
| Provision for inventory obsolescence | 5,055 | - |
| Deferred taxes | (1,505) | - |
| Share-based compensation | 5,316 | 4,657 |
| Minority interest | 28 | 235 |
| Amortization of step up of fair value in inventory | - | 242 |
| Gain on sale of Pain Care® operations | - | (1,570) |
| Other | 938 | 515 |
| Change in operating assets and liabilities: | | |
| Restricted cash | (4,592) | 4,772 |
| Accounts receivable | (10,741) | (10,630) |
| Inventories | (5,655) | (16,734) |
| Prepaid expenses and other current assets | (2,261) | (4,486) |
| Accounts payable | (577) | 3,250 |
| Current liabilities | 7,954 | (5,839) |
| Net cash provided by operating activities | 16,983 | 2,254 |
| Cash flows from investing activities: | | |
| Capital expenditures | (9,153) | (12,150) |
| Proceeds from sale of Pain Care® operations | - | 5,980 |
| Net cash used in investing activities | (9,153) | (6,170) |
| Cash flows from financing activities: | | |
| Net proceeds from issuance of common shares | 7 | 1,922 |
| Repayments of long-term debt | (16,618) | (5,351) |
| Proceeds from (repayments of) bank borrowings, net | 1,107 | (1,131) |
| Cash payment for purchase of minority interest in subsidiary | (1,143) | - |
| Tax benefit on non-qualified stock options | 2 | 22 |
| Net cash used in financing activities | (16,645) | (4,538) |
| Effect of exchange rate changes on cash | 139 | 235 |
| Net decrease in cash and cash equivalents | (8,676) | (8,219) |
| Cash and cash equivalents at the beginning of the year | 14,594 | 25,064 |
| Cash and cash equivalents at the end of the period | \$5,918 | \$16,845 |

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

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NOTES TO THE CONDENSED UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: BUSINESS

Orthofix International N.V. (the “Company”) is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical equipment, principally for the Orthopedic products market. The Company is made up of four reportable segments: Domestic, Spinal Implants and Biologics, Breg and International. See Note 13 for a description of each segment.

NOTE 2: BASIS OF PRESENTATION

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States 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 United States, 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 and six months ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. The balance sheet at December 31, 2008 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 United States 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, 2008.

NOTE 3: RECENTLY ISSUED ACCOUNTING STANDARDS

In January 2009, the Company adopted Emerging Issues Task Force (“EITF”) Issue No. 07-1, “Accounting for Collaborative Arrangements” (“EITF 07-1”). EITF 07-1 provides guidance related to the classification of the payments between participants, the appropriate income statement presentation, as well as disclosures related to certain collaborative arrangements. The adoption of EITF 07-1 did not have a material impact on the Company’s results of operations or financial position, as the Company had previously applied the guidance included in EITF 07-1 since there was no prevailing authoritative guidance.

In January 2009, the Company adopted Statement of Financial Accounting Standards (“SFAS”) No. 160, “Non-controlling Interests in Consolidated Financial Statements, an Amendment of ARB 51” (“SFAS No. 160”). SFAS No. 160 establishes accounting and reporting standards pertaining to ownership interest in subsidiaries held by parties other than the parent, the amount of net income attributable to the parent and to the non-controlling interest, changes in a parent’s ownership interest, and the valuation of any retained non-controlling equity investment when a subsidiary is deconsolidated. SFAS No. 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. SFAS No. 160 and its adoption changed the method in which the Company accounted for the minority interest acquisition during the first half of 2009. SFAS No. 160 requires the excess purchase price over the minority interest liability (at the time of the acquisition) to be recorded as a capital transaction. The disclosure requirements of SFAS No. 160 did not have an impact on the Company’s financial reporting as the remaining minority interest liability is immaterial.

In May 2009, the FASB issued SFAS No. 165, “Subsequent Events” (“SFAS No. 165”). SFAS No. 165 provides authoritative accounting literature for a topic that was previously addressed only in auditing literature (AICPA AU Section 560, Subsequent Events). The guidance in SFAS No. 165 is largely similar to the current guidance in the auditing literature with some exceptions that are not intended to result in significant changes in practice. Three

modifications to the subsequent events guidance in AU Section 560 are: 1) to name the two types of subsequent events either as recognized subsequent events (currently referred to in practice as Type I subsequent events) or non-recognized subsequent events (currently referred to in practice as Type II subsequent events), 2) to modify the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued for public entities and 3) to require entities to disclose the date through which an entity has evaluated subsequent events and the basis for that date. SFAS No. 165 is effective for interim or annual financial periods ending after June 15, 2009 and should be applied prospectively. The Company has determined that the disclosure requirements of SFAS No. 165 do not have an impact on the Company's financial reporting or disclosure requirements as of June 30, 2009. In accordance with the provisions of SFAS No. 165, the Company has evaluated all subsequent events that occurred through July 31, 2009, the date the financial statements were issued.

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NOTE 4: SHARE-BASED COMPENSATION

The Company accounts for its share-based compensation plans in accordance with SFAS No. 123(R), "Share-Based Payment". Under SFAS No. 123(R), 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 statement 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 for the three and six months ended June 30, 2009 and 2008:

| (US\$ in thousands) | Three Months Ended | | Six Months Ended | |
|----------------------------|--------------------|------------------|------------------|------------------|
| | June 30, 2009 | June 30, 2008 | June 30, 2009 | June 30, 2008 |
| Cost of sales | \$142 | \$79 | \$339 | \$192 |
| Sales and marketing | 773 | 590 | 1,665 | 774 |
| General and administrative | 1,470 | 1,720 | 3,024 | 3,284 |
| Research and development | 107 | 174 | 288 | 407 |
| Total | \$2,492 | \$2,563 | \$5,316 | \$4,657 |

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

NOTE 5: RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform to the 2009 presentation. The reclassifications have no effect on previously reported net income or shareholders' equity.

NOTE 6: 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 FIFO method. The valuation of work-in-process, finished goods, field inventory and consignment inventory includes the cost of materials, labor and production. Field inventory represents immediately saleable finished goods inventory that is in the possession of the Company's direct sales representatives.

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Inventories were as follows:

| (US\$ in thousands) | June 30, 2009 | December 31, 2008 |
|-------------------------------|------------------|----------------------|
| Raw materials | \$9,431 | \$ 9,314 |
| Work-in-process | 8,497 | 8,829 |
| Finished products | 60,263 | 57,151 |
| Field inventory | 15,521 | 13,633 |
| Consignment inventory | 24,820 | 23,426 |
| | 118,532 | 112,353 |
| Less reserve for obsolescence | (24,360) | (21,168) |
| | \$94,172 | \$ 91,185 |

NOTE 7: GOODWILL

The changes in the carrying value of goodwill by reportable segment for the period ended June 30, 2009 are as follows:

| (US\$ in thousands) | Domestic | Spinal Implants and Biologics | Breg | International | Total |
|----------------------|----------|--|----------|---------------|-----------|
| At December 31, 2008 | \$31,793 | \$9,367 | \$99,295 | \$ 42,126 | \$182,581 |
| Foreign currency | - | - | - | 2,689 | 2,689 |
| At June 30, 2009 | \$31,793 | \$9,367 | \$99,295 | \$ 44,815 | \$185,270 |

NOTE 8: PATENTS AND OTHER INTANGIBLE ASSETS

(US\$ in thousands)

| | June 30, 2009 | December 31, 2008 |
|---|------------------|----------------------|
| Cost | | |
| Patents and developed technologies | \$29,599 | \$ 25,602 |
| Trademarks – definite lived (subject to amortization) | 119 | 105 |
| Trademarks – indefinite lived (not subject to amortization) | 23,460 | 23,382 |
| Distribution networks | 44,586 | 44,586 |
| | 97,764 | 93,675 |
| Accumulated amortization | | |
| Patents and developed technologies | (17,850) | (13,194) |
| Trademarks – definite lived (subject to amortization) | (119) | (105) |
| Distribution networks | (28,902) | (26,830) |
| Patents and other intangible assets, net | \$50,893 | \$ 53,546 |

Amortization expense for intangible assets is estimated to be approximately \$3.0 million for the remainder of 2009 and \$5.9 million, \$5.9 million, \$4.6 million, \$1.5 million and \$6.4 million for the periods ending December 31, 2010, 2011, 2012, 2013, and thereafter, respectively.

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NOTE 9: BANK BORROWINGS

| (US\$ in thousands) | June 30, 2009 | December 31, 2008 |
|---------------------------------|------------------|----------------------|
| Borrowings under line of credit | \$ 3,080 | \$ 1,907 |

The weighted average interest rates on borrowings under lines of credit as of June 30, 2009 and December 31, 2008 were 4.97% and 5.86%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 5.1 million Euros (\$7.2 million) and 5.2 million Euros (\$7.3 million) at June 30, 2009 and December 31, 2008, respectively, in its Italian line of credit, which gives the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing. This line of credit is unsecured.

NOTE 10: LONG-TERM DEBT

| (US\$ in thousands) | June 30, 2009 | December 31, 2008 |
|-----------------------|------------------|----------------------|
| Long-term obligations | \$ 264,050 | \$ 280,700 |
| Other loans | 193 | 162 |
| | 264,243 | 280,862 |
| Less current portion | (3,333) | (3,329) |
| | \$ 260,910 | \$ 277,533 |

On September 22, 2006 the Company's wholly-owned US holding company subsidiary, Orthofix Holdings, Inc. ("Orthofix Holdings"), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone Medical Inc. ("Blackstone"). Certain terms of the senior secured credit facility were amended September 29, 2008. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million and (2) a six-year revolving credit facility of \$45.0 million. As of June 30, 2009, the Company had no amounts outstanding under the revolving credit facility and \$264.1 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of the London Inter-Bank Offered Rate ("LIBOR") plus a margin, with a LIBOR floor of 3.0% or prime rate plus a margin. Currently, the term loan includes a \$150.0 million LIBOR loan plus a margin of 4.50% and \$114.1 million prime rate loan plus a margin of 3.50%. The effective interest rates on the senior secured credit facility, including the impact of an interest rate swap (see Note 17), as of June 30, 2009 and December 31, 2008 were 8.6% and 8.4%, respectively.

Each of the domestic subsidiaries of the Company (which includes Orthofix Inc., Breg Inc., and Blackstone) and Colgate Medical Limited and Victory Medical Limited (wholly-owned financing subsidiaries of the Company) has guaranteed the obligations of Orthofix Holdings under the senior secured credit facility. The obligations of the subsidiaries under their guarantees are secured by the pledges of their respective assets.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's senior secured credit facility. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of June 30, 2009 is \$123.2 million compared to \$111.3 million at December 31, 2008. In addition, the senior secured credit facility restricts the Company and subsidiaries that are not parties to

the credit facility from access to cash held by Colgate Medical Limited and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of June 30, 2009 is \$15.6 million compared to \$11.0 million at December 31, 2008.

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Weighted average interest rates on current maturities of long-term obligations as of June 30, 2009 and December 31, 2008 were 8.6% and 8.4%, respectively.

NOTE 11: COMMON SHARES

During the six month period ended June 30, 2009, there were 26,477 shares of common stock issued upon the vesting of restricted stock and the exercise of outstanding stock options.

NOTE 12: COMPREHENSIVE INCOME (LOSS)

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and the effective portion of the gain (loss) for derivatives designated and accounted for as cash flow hedges. The components of and changes in accumulated other comprehensive income are as follows:

| (US\$ in thousands) | Foreign Currency Translation Adjustments | Fair Value of Derivative | Accumulated Other Comprehensive Income/(Loss) |
|--|---|-----------------------------|--|
| Balance at December 31, 2008 | \$ (211) | \$ 3,097 | \$ 2,886 |
| Unrealized loss on derivative instruments, net of tax of \$(1,004) | - | (2,585) | (2,585) |
| Foreign currency translation adjustment | 5,221 | - | 5,221 |
| Balance at June 30, 2009 | \$ 5,010 | \$ 512 | \$ 5,522 |

Comprehensive income is comprised of the following components:

| (US\$ in thousands) | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|---------|------------------------------|----------|
| | 2009 | 2008 | 2009 | 2008 |
| Net income | \$5,944 | \$5,808 | \$8,823 | \$9,414 |
| Other comprehensive income: | | | | |
| Unrealized gain (loss) on derivative instrument, net of tax | (696) | (903) | (2,585) | 1,921 |
| Foreign currency translation adjustment | 6,147 | 1,798 | 5,221 | 171 |
| Total comprehensive income | \$11,395 | \$6,703 | \$11,459 | \$11,506 |

NOTE 13: 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. The Company is comprised of the following segments:

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Domestic

Domestic (“Domestic”) consists of operations in the United States of Orthofix Inc., which designs, manufactures and distributes stimulation, orthopedic and biologics products. Domestic uses both direct and distributor sales representatives to sell Spine and Orthopedic products to hospitals, doctors and other healthcare providers in the United States market.

Spinal Implants and Biologics

Spinal Implants and Biologics (“Spinal Implants and Biologics”) consists of Blackstone and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Spinal Implants and Biologics specializes in the design, development and marketing of spinal implant and related human cellular and tissue based products (“HCT/P products”, often referred to as Biologic products). Spinal Implants and Biologics distributes its products through a network of domestic and international distributors, sales representatives and affiliates.

Breg

Breg, Inc. (“Breg”), based in Vista, California, designs, manufactures, and distributes orthopedic products for post-operative reconstruction and rehabilitative patient use and sells its products through a network of domestic and international distributors, sales representatives and affiliates.

International

International (“International”) consists of international operations located in Europe, Mexico, Brazil and Puerto Rico, as well as independent distributors located outside the United States. International uses both direct and distributor sales representatives to sell Spine, Orthopedics, Sports Medicine, Vascular and Other products to hospitals, doctors, and other healthcare providers.

Group Activities

Group activities are comprised of the operating expenses of Orthofix International N.V. and its US holding company subsidiary, Orthofix Holdings, Inc.

The following tables below present information by reportable segment for the three and six months ended June 30:

For the three month period ended June 30:

| (US\$ in thousands) | External Sales | | Intersegment Sales | |
|-----------------------------|----------------|------------|--------------------|-----------|
| | 2009 | 2008 | 2009 | 2008 |
| Domestic | \$ 53,635 | \$ 47,205 | \$ 2,128 | \$ 1,683 |
| Spinal Implants & Biologics | 30,025 | 26,924 | 1,308 | 1,064 |
| Breg | 23,342 | 21,901 | 1,383 | 1,118 |
| International | 30,544 | 34,009 | 5,788 | 7,935 |
| Total | \$ 137,546 | \$ 130,039 | \$ 10,607 | \$ 11,800 |

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For the six month period ended June 30:

| (US\$ in thousands) | External Sales | | Intersegment Sales | |
|-----------------------------|----------------|------------|--------------------|-----------|
| | 2009 | 2008 | 2009 | 2008 |
| Domestic | \$ 103,432 | \$ 91,332 | \$ 3,708 | \$ 3,304 |
| Spinal Implants & Biologics | 58,544 | 55,755 | 1,674 | 2,589 |
| Breg | 46,452 | 43,964 | 2,893 | 2,656 |
| International | 58,092 | 67,020 | 10,427 | 13,433 |
| Total | \$ 266,520 | \$ 258,071 | \$ 18,702 | \$ 21,982 |

The following table presents operating income (loss) by segment for the three and six months ended June 30:

| (US\$ in thousands) | Three Months Ended June 30, | | Six Months Ended June 30, | |
|-------------------------------|--------------------------------|-----------|------------------------------|-----------|
| | 2009 | 2008 | 2009 | 2008 |
| Domestic | \$ 17,853 | \$ 15,947 | \$ 34,505 | \$ 30,080 |
| Spinal Implants and Biologics | (6,735)(1) | (6,985) | (14,468)(2) | (10,792) |
| Breg | 2,987 | 2,696 | 6,017 | 7,067 |
| International | 3,776 | 5,147 | 7,450 | 9,710 |
| Group Activities | (4,685) | (4,401) | (10,157) | (12,216) |
| Eliminations | 449 | (867) | 798 | (721) |
| Total | \$ 13,645 | \$ 11,537 | \$ 24,145 | \$ 23,128 |

(1) Includes \$2.1 million of research and development expense from collaborative arrangements and \$1.7 million of restructuring charges.

(2) Includes \$4.9 million of research and development expense from collaborative arrangements and \$3.0 million of restructuring charges.

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The following tables present sales by market sector for the three and six months ended June 30, 2009 and 2008:

Sales by Market Sector
for the three month period ended June 30, 2009

| (US\$ in thousands) | Domestic | Spinal Implants & Biologics | Breg | International | Total |
|---------------------|-----------------|-----------------------------------|-----------------|------------------|------------------|
| Spine | \$40,142 | \$30,025 | \$- | \$ 565 | \$70,732 |
| Orthopedics | 13,493 | - | - | 19,133 | 32,626 |
| Sports Medicine | - | - | 23,342 | 1,118 | 24,460 |
| Vascular | - | - | - | 4,262 | 4,262 |
| Other | - | - | - | 5,466 | 5,466 |
| Total | \$53,635 | \$30,025 | \$23,342 | \$ 30,544 | \$137,546 |

Sales by Market Sector
for the three month period ended June 30, 2008

| (US\$ in thousands) | Domestic | Spinal Implants & Biologics | Breg | International | Total |
|---------------------|-----------------|-----------------------------------|-----------------|------------------|------------------|
| Spine | \$35,430 | \$26,924 | \$- | \$ 358 | \$62,712 |
| Orthopedics | 11,775 | - | - | 21,559 | 33,334 |
| Sports Medicine | - | - | 21,901 | 1,288 | 23,189 |
| Vascular | - | - | - | 3,741 | 3,741 |
| Other | - | - | - | 7,063 | 7,063 |
| Total | \$47,205 | \$26,924 | \$21,901 | \$ 34,009 | \$130,039 |

Table of ContentsSales by Market Sector
for the six month period ended June 30, 2009

| (US\$ in thousands) | Domestic | Spinal Implants & Biologics | Breg | International | Total |
|---------------------|------------------|-----------------------------------|-----------------|------------------|------------------|
| Spine | \$77,425 | \$58,544 | \$- | \$ 891 | \$136,860 |
| Orthopedics | 26,007 | - | - | 36,212 | 62,219 |
| Sports Medicine | - | - | 46,452 | 2,254 | 48,706 |
| Vascular | - | - | - | 8,670 | 8,670 |
| Other | - | - | - | 10,065 | 10,065 |
| Total | \$103,432 | \$58,544 | \$46,452 | \$ 58,092 | \$266,520 |

Sales by Market Sector
for the six month period ended June 30, 2008

| (US\$ in thousands) | Domestic | Spinal Implants & Biologics | Breg | International | Total |
|---------------------|-----------------|-----------------------------------|-----------------|------------------|------------------|
| Spine | \$68,803 | \$55,755 | \$- | \$ 612 | \$125,170 |
| Orthopedics | 22,529 | - | - | 40,566 | 63,095 |
| Sports Medicine | - | - | 43,964 | 2,548 | 46,512 |
| Vascular | - | - | - | 9,117 | 9,117 |
| Other | - | - | - | 14,177 | 14,177 |
| Total | \$91,332 | \$55,755 | \$43,964 | \$ 67,020 | \$258,071 |

NOTE 14:

RESTRUCTURING CHARGES

In the fourth quarter of 2008, the Company initiated a restructuring plan to improve operations and reduce costs at Blackstone. The plan involves the consolidation of substantially all of Blackstone's current operations in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and US orthopedics business in the Dallas, TX area. During the three and six months ended June 30, 2009, the Company recorded net restructuring charges of \$1.7 and \$3.0 million, respectively, which were primarily related to severance costs and accelerated depreciation costs related to shortening lives of assets which will be disposed. These restructuring costs are recorded in general and administrative expense and are classified in the Spinal Implants and Biologics segment. The Company plans to complete the restructuring and consolidation by the fourth quarter of 2009.

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NOTE 15:

INCOME TAXES

The reported tax provision as a percentage of income before income taxes was 35.0%. The principal factors affecting the Company's tax rate relate to the benefits associated with the Company's mix of earnings and a restructuring of the Company's European operations in 2006 to optimize the Company's supply chain, which resulted in tax efficiencies, principally offset by the generation of current period un-benefitted net operating losses in various foreign jurisdictions.

As of June 30, 2009, the Company's gross unrecognized tax benefit was \$0.7 million. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within its global operations in income tax expense. As of June 30, 2009, the Company had approximately \$0.4 million accrued for interest and penalties. The entire \$1.1 million of unrecognized tax benefit would affect the Company's effective tax rate if recognized. The Company does not expect the amount of unrecognized tax benefits to change significantly over the next twelve months.

The Company is subject to tax examinations in all major taxing jurisdictions in which it operates. The Company files a consolidated income tax return in the US federal jurisdiction and numerous consolidated and separate income tax returns in many state and foreign jurisdictions. The statute of limitations with respect to US federal tax filings is closed for years prior to December 31, 2004. The statute of limitations for the various US state tax filings is closed in most instances for years prior to December 31, 2005. The Company is currently under examination by the Internal Revenue Service ("IRS") for the tax years ended December 31, 2005 and December 31, 2006. There have been no issues raised to date by the IRS that would require an adjustment to the current level of unrecognized tax benefits. There are certain US state tax statutes open for years from 1997 forward due to current examinations. The statutes of limitations with respect to the major foreign tax filing jurisdictions are generally closed for years prior to December 31, 2004.

NOTE 16:

EARNINGS PER SHARE

For the three and six months ended June 30, 2009 and 2008, there were no adjustments to net income for purposes of calculating basic and diluted net income per common share. The following table is a reconciliation of the weighted average shares used in the basic and diluted net income per common share computations.

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|--------------------------------|------------|------------------------------|------------|
| | 2009 | 2008 | 2009 | 2008 |
| Weighted average common shares - basic | 17,107,084 | 17,090,217 | 17,105,323 | 17,088,735 |
| Effect of dilutive securities | 65,473 | 25,798 | 34,466 | 151,269 |
| Weighted average common shares – diluted | 17,172,557 | 17,116,015 | 17,139,789 | 17,240,004 |

For the three and six months ended June 30, 2009, the Company did not include 3,162,373 and 3,189,859 options, respectively, in the diluted shares outstanding calculation because their inclusion would have been anti-dilutive or because their exercise price exceeded the average market price of the Company's common stock during the period.

For the three and six months ended June 30, 2008, the Company did not include 2,147,299 and 1,073,120 options, respectively, in the diluted shares outstanding calculation because their inclusion would have been anti-dilutive or because their exercise price exceeded the average market price of the Company's common stock during the period.

NOTE 17:

DERIVATIVE INSTRUMENTS

In 2006, the Company entered into a cross-currency swap agreement to manage its foreign currency exposure related to a portion of the Company's intercompany receivable of a US dollar functional currency subsidiary that is denominated in Euro. The derivative instrument, a ten-year fully amortizable agreement with a notional amount of \$63.0 million, is scheduled to expire on December 30, 2016. The instrument is designated as a cash flow hedge. The amount outstanding under the agreement as of June 30, 2009 and December 31, 2008 is \$56.7 million. Under the agreement, the Company pays Euro and receives US dollars based on scheduled cash flows in the agreement. The Company recognized an unrealized loss on the change in fair value of this swap arrangement of \$(0.7) million and \$(2.6) million, net of tax, within other comprehensive income in the three and six months ended June 30, 2009, respectively. In 2008, the Company recognized an unrealized gain (loss) on the change in fair value of this swap arrangement of \$(0.9) million and \$1.9 million, net of tax, within other comprehensive income in the three and six months ended June 30, 2008, respectively.

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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 second and third quarters of 2008, the interest rate Swap was accounted for as a cash flow hedge, and changes in its value were recorded as part of accumulated other comprehensive income on the balance sheet. Due to declining interest rates and a LIBOR floor in the Company's amended credit facility, the Swap was no longer deemed highly effective. Therefore, during the fourth quarter of 2008, the Company incurred an unrealized, non-cash loss of approximately \$8.0 million which resulted from changes in the fair value of the Company's interest rate Swap. Cash flow accounting is no longer applied and mark-to-market adjustments are required to be reported in current earnings through the expiration of the Swap in June 2011. For the three and six months ended June 30, 2009, the Company recorded an unrealized gain of \$1.0 and \$1.3 million, respectively, in other income (expense), net on the statement of operations. For the three and six months ended June 30, 2008, the Company recognized an unrealized gain on the change in the fair value of the Swap of \$0.7 million, net of tax, within other comprehensive income. The Swap continues to provide an economic hedge against fluctuating interest rate exposure on the \$150.0 million portion of outstanding debt it covers, should the LIBOR interest rate rise above 3.73%.

As required by SFAS No. 161 “Disclosures about Derivative Instruments and Hedging Activities” (“SFAS No. 161”), the tables below disclose the types of derivative instruments the Company owns, the classifications and fair values of these instruments within the balance sheet, and the amount of gain (loss) recognized in other comprehensive income (“OCI”) or income.

(US\$ in thousands)

| As of June 30, 2009 | Fair value: favorable (unfavorable) | Balance sheet location | Amount of gain (loss) recognized in OCI |
|---------------------|---|---------------------------|--|
| | | Other long-term | |
| Cross-currency swap | \$ (3,200) | liabilities | \$ (2,585) |
| | | Other current | |
| Interest rate swap | \$ (6,700) | liabilities | \$ - |

| As of June 30, 2008 | Fair value: favorable (unfavorable) | Balance sheet location | Amount of gain (loss) recognized in OCI |
|---------------------|---|---------------------------|--|
| | | Other long-term | |
| Cross-currency swap | \$ (8,270) | liabilities | \$ 1,921 |
| Interest rate swap | \$ 1,047 | Other current assets | \$ 681 |

(US\$ in thousands)

| Amount of gain (loss) recognized in income | For the three months ended June 30, | | For the six months ended June 30, | |
|--|--|------|--------------------------------------|------|
| | 2009 | 2008 | 2009 | 2008 |
| Interest rate swap | \$1,036 | \$- | \$1,275 | \$- |

NOTE 18:

FAIR VALUE MEASUREMENTS

The Company adopted SFAS No. 157, “Fair Value Measurements” effective January 1, 2008. SFAS No. 157 defines fair value 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. SFAS No. 157 also describes three levels of inputs that may be used to measure fair value:

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Level 1 – quoted prices in active markets for identical assets and liabilities

Level 2 – observable inputs other than quoted prices in active markets for identical assets and liabilities

Level 3 – unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

As of June 30, 2009, the Company held certain items that are required to be measured at fair value on a recurring basis. These included cash equivalents, an interest rate derivative contract, and a cross currency derivative contract. Cash equivalents consist of short-term, highly liquid, income-producing investments, all of which have maturities of 90 days or less, including money market funds. Derivative instruments are related to the Company's interest rate and foreign currency hedges.

The Company's cross currency derivative instrument consists of an over-the-counter (OTC) contract, which is not traded on a public exchange. The fair value of 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 Level 2. 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 Company's interest rate derivative instrument also consists of an OTC swap contract. The inputs used to determine the fair value of this contract are obtained in quoted public markets. Therefore, the Company has categorized the swap contract as Level 2. 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 measured at fair value on a recurring basis were as follows:

| | Balance June 30, 2009 | Level 1 | Level 2 | Level 3 |
|-------------------------------------|-----------------------------|---------|------------|---------|
| Derivative Financial Instruments(1) | | | | |
| Cash Flow Hedges | | | | |
| Interest rate hedge | \$(6,700) | \$- | \$(6,700) | \$- |
| Cross currency hedge | \$(3,200) | \$- | \$(3,200) | \$- |

(1) See Note 17, "Derivative Instruments".

NOTE 19:

CONTINGENCIES

Litigation

On or about July 23, 2007, our subsidiary, 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 us 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.

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On or about January 7, 2008, the Company received a federal grand jury subpoena from the United States 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 for the Company received a HIPAA subpoena issued by the US 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, as well as the January 7, 2008 federal grand jury subpoena. On or about June 15, 2009, Orthofix, Inc., and Blackstone, executed an agreement with the United States Attorney's Office for the District of Massachusetts (the "Tolling Agreement") extending an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate. The Tolling Agreement extended the period tolling the statute of limitations to include the period from December 1, 2008 through and including December 31, 2009.

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 US 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 US Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. On November 21, 2008, the US 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 United States Attorney's Office for the District of Massachusetts. 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 US 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 us resulting from this matter.

On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the United States 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 Company believes that the CID seeks documents concerning Blackstone's financial relationships with certain physicians and related matters for the period from March 2004 through the date of issuance of the CID. 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 us resulting from the USAO-Nevada subpoena, the Massachusetts CID and the Ohio AG subpoena.

By order entered on January 4, 2007, the United States 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 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 us 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.

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The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund and there can be no assurance that losses to us from these matters will not exceed the amount of the escrow account. As of June 30, 2009 and December 31, 2008, included in Prepaid expenses and other current assets is approximately \$11.5 million and \$8.3 million of escrow receivable balances related to the Blackstone matters described above, respectively.

In addition to the foregoing claims, the Company has submitted claims for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for losses that have 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 Blackstone's 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.

On or about April 10, 2009, the Company received a HIPAA subpoena ("HIPAA subpoena") issued by the US Attorney's Office for the District of Massachusetts. The subpoena seeks documents for the period January 1, 1995 through the date of the subpoena. The Company believes that the subpoena concerns the classification and marketing of its bone growth stimulators and related matters. The Company intends to cooperate with the government's requests. The Company is unable to predict what actions, if any, might be taken by the government or what impact, if any, the outcome of this matter might have on the Company's consolidated financial position, results of operations or cash flows.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the US District Court for the District of Massachusetts against Orthofix, Inc., the Company, 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 amended 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 amended 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. To the best of the Company's knowledge, the plaintiff has not served either Orthofix, Inc. or the Company. If served, the Company intends to defend vigorously against this lawsuit.

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 US District Court for the District of Massachusetts against the Company. This complaint has been consolidated with the complaint described in the immediately preceding paragraph, and was unsealed on June 30, 2009. The amended complaint alleges violations of the False Claims Act, fraudulent billing, illegal kickbacks, wrongful termination, conspiracy, and violations of the Sherman Anti-trust Act based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products, provided physicians kickbacks in the form of free units, referral fees, and fitting fees, and that the defendant and its competitors discussed together strategies to encourage higher government pricing for the products. The amended complaint also alleges that TRICARE has been reimbursing for the Company's Cervical Stim product without approval to do so. To the best of the Company's knowledge the plaintiff has not served the Company. If served, the Company intends to defend vigorously against this lawsuit.

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 US patents and that Blackstone's making, selling, offering for sale, and using its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products within the United States 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 Company's 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 us 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.

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The Company cannot predict the outcome of any proceedings 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 our consolidated financial position, results of operations, or cash flows.

In addition to the foregoing, in the normal course of our business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies.

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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 the results of our operations for the three and six months ended June 30, 2009 compared to our results of operations for the three and six months ended June 30, 2008. 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 Form 10-Q and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

General

We are a diversified orthopedic products company offering a broad line of surgical and non-surgical products for the Spine, Orthopedics, Sports Medicine and Vascular market sectors. 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 enhancing venous circulation, cold therapy, bone cement and devices for removal of bone cement used to fix artificial implants and airway management products used in anesthesia applications.

We have administrative and training facilities in the United States and Italy and manufacturing facilities in the United States, the United Kingdom, Italy and Mexico. We directly distribute our products in the United States, the United Kingdom, Italy, Germany, Switzerland, Austria, France, Belgium, Mexico, Brazil, and Puerto Rico. In several of these and other markets, we also distribute our products through independent distributors.

Our condensed consolidated financial statements include the financial results of the Company and its 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 United States Dollar. All balance sheet accounts, except shareholders' equity, are translated at period-end exchange rates, and revenue and expense items are translated at weighted average rates of exchange prevailing during the period. Gains and losses resulting from foreign currency transactions are included in other income. Gains and losses resulting from the translation of foreign currency financial statements are recorded in the accumulated other comprehensive income component of shareholders' equity.

Our financial condition, results of operations and cash flows are not significantly impacted by seasonality trends. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. Certain of the Breg bracing products experience greater demand in the fall and winter corresponding with high school and college football schedules and winter sports. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar income and expenditures. During the six months ended June 30, 2009 and all of 2008, we have used derivative instruments to hedge certain foreign currency fluctuation exposures as well as interest rate exposure on LIBOR-based borrowings. See Item 3 – "Quantitative and Qualitative Disclosures About Market Risk."

We manage our operations as four business segments: Domestic, Spinal Implants and Biologics, Breg, and International. Domestic consists of operations of our subsidiary Orthofix Inc. Spinal Implants and Biologics consist of our Blackstone subsidiary and its domestic and international operations. Breg consists of Breg Inc.'s operations and domestic and international distributors. International consists of operations which are located in the rest of the world as well as independent export distribution operations. Group Activities are comprised of the operating expenses and identifiable assets of Orthofix International N.V. and its US holding company subsidiary, Orthofix Holdings, Inc.

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Segment and Market Sector Revenues

The following tables display net sales by business segment and net sales by market sector. We keep our books and records and account for net sales, costs of sales and expenses by business segment. We provide net sales by market sector for information purposes only.

Business Segment:

| (US\$ in thousands) | Three Months Ended June 30, | | | | | | | |
|-------------------------------|-----------------------------|----------------------------------|--|-----------|----------------------------------|--|--------|--|
| | 2009 | | | | 2008 | | | |
| | Net Sales | Percent of Total Net Sales | | Net Sales | Percent of Total Net Sales | | Growth | |
| Domestic | \$53,635 | 39 % | | \$47,205 | 36 % | | 14 % | |
| Spinal Implants and Biologics | 30,025 | 22 % | | 26,924 | 21 % | | 12 % | |
| Breg | 23,342 | 17 % | | 21,901 | 17 % | | 7 % | |
| International | 30,544 | 22 % | | 34,009 | 26 % | | -10 % | |
| Total | \$137,546 | 100 % | | \$130,039 | 100 % | | 6 % | |

| (US\$ in thousands) | Six Months Ended June 30, | | | | | | | |
|-------------------------------|---------------------------|----------------------------------|--|-----------|----------------------------------|--|--------|--|
| | 2009 | | | | 2008 | | | |
| | Net Sales | Percent of Total Net Sales | | Net Sales | Percent of Total Net Sales | | Growth | |
| Domestic | \$103,432 | 39 % | | \$91,332 | 35 % | | 13 % | |
| Spinal Implants and Biologics | 58,544 | 22 % | | 55,755 | 22 % | | 5 % | |
| Breg | 46,452 | 17 % | | 43,964 | 17 % | | 6 % | |
| International | 58,092 | 22 % | | 67,020 | 26 % | | -13 % | |
| Total | \$266,520 | 100 % | | \$258,071 | 100 % | | 3 % | |

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Market Sector:

(US\$ in thousands)

Three Months Ended June 30,

| | 2009 | | | 2008 | | | Reported Growth | Constant Currency Growth |
|-----------------|------------------|----------------------------|--|------------------|----------------------------|--|-----------------|--------------------------|
| | Net Sales | Percent of Total Net Sales | | Net Sales | Percent of Total Net Sales | | | |
| Spine | \$70,732 | 51 % | | \$62,712 | 48 % | | 13 % | 13 % |
| Orthopedics | 32,626 | 24 % | | 33,334 | 26 % | | -2 % | 9 % |
| Sports Medicine | 24,460 | 18 % | | 23,189 | 18 % | | 5 % | 6 % |
| Vascular | 4,262 | 3 % | | 3,741 | 3 % | | 14 % | 20 % |
| Other | 5,466 | 4 % | | 7,063 | 5 % | | -23 % | -4 % |
| Total | \$137,546 | 100 % | | \$130,039 | 100 % | | 6 % | 10 % |

(US\$ in thousands)

Six Months Ended June 30,

| | 2009 | | | 2008 | | | Reported Growth | Constant Currency Growth |
|-----------------|------------------|----------------------------|--|------------------|----------------------------|--|-----------------|--------------------------|
| | Net Sales | Percent of Total Net Sales | | Net Sales | Percent of Total Net Sales | | | |
| Spine | \$136,860 | 52 % | | \$125,170 | 49 % | | 9 % | 10 % |
| Orthopedics | 62,219 | 23 % | | 63,095 | 24 % | | -1 % | 9 % |
| Sports Medicine | 48,706 | 18 % | | 46,512 | 18 % | | 5 % | 6 % |
| Vascular | 8,670 | 3 % | | 9,117 | 4 % | | -5 % | 1 % |
| Other | 10,065 | 4 % | | 14,177 | 5 % | | -29 % | -10 % |
| Total | \$266,520 | 100 % | | \$258,071 | 100 % | | 3 % | 7 % |

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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 June 30, | | Six Months Ended June 30, | |
|---------------------------------------|--------------------------------|-------------|------------------------------|-------------|
| | 2009 (%) | 2008 (%) | 2009 (%) | 2008 (%) |
| Net sales | 100 | 100 | 100 | 100 |
| Cost of sales | 27 | 27 | 26 | 27 |
| Gross profit | 73 | 73 | 74 | 73 |
| Operating expenses | | | | |
| Sales and marketing | 40 | 41 | 40 | 40 |
| General and administrative | 15 | 14 | 17 | 16 |
| Research and development | 7 | 5 | 7 | 5 |
| Amortization of intangible assets | 1 | 4 | 1 | 4 |
| Gain on sale of Pain Care® operations | - | - | - | (1) |
| Total operating income | 10 | 9 | 9 | 9 |
| Net income | 4 | 4 | 3 | 4 |

Three Months Ended June 30, 2009 Compared to Three Months Ended June 30, 2008

Net sales increased 6% to \$137.5 million in the second quarter of 2009 compared \$130.0 million for the same period last year. The impact of foreign currency decreased sales by \$5.5 million during the second quarter of 2009 when compared to the second quarter of 2008.

Sales by Business Segment:

Net sales in Domestic increased to \$53.6 million in the second quarter of 2009 compared to \$47.2 million for the same period last year, an increase of 14%. Domestic's net sales represented 39% and 36% of total net sales during the second quarter of 2009 and 2008, respectively. The increase in Domestic's net sales was partially the result of a 13% increase in sales in our Spine market sector, which was mainly driven by the increase in sales of our Spinal-Stim® and Cervical-Stim® products. The increase in Domestic's net sales was also attributable to the 15% increase in our Orthopedic market sector which included a 14% increase in sales of Physio-Stim® products as compared to the prior year period. Also attributing to the growth in the Orthopedic market sector is an \$0.8 million, or 92% increase, in sales of human cellular and tissue based products ("HCT/P products", often referred to as Biologics products) used in orthopedic applications when comparing these same two periods. Our biologics sales include sales of Trinity® and sales from the limited market release of our new Trinity® Evolution™ stem cell-based allograft.

Domestic Sales by Market Sector:

| (US\$ in thousands) | Net Sales for the Three Months Ended June 30, | | Growth |
|---------------------|--|-----------|--------|
| | 2009 | 2008 | |
| Spine | \$ 40,142 | \$ 35,430 | 13 % |
| Orthopedics | 13,493 | 11,775 | 15 % |
| Total | \$ 53,635 | \$ 47,205 | 14 % |

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Net sales in Spinal Implants and Biologics increased \$3.1 million to \$30.0 million in the second quarter of 2009 compared to \$26.9 million for the same period last year, an increase of 12%. Spinal Implants and Biologics' net sales represented 22% and 21% of total net sales during the second quarter of 2009 and 2008, respectively. The increase in sales was primarily related to thoracolumbar product sales due to the introduction of the new Firebird™ pedicle screw system, during the second quarter of 2009. Sales of our thoracolumbar products increased 20% and sales of our biologics products increased 12% when compared to the same period last year. Our biologics sales include sales of Trinity® and sales from the limited market release of our new Trinity® Evolution™ stem cell-based allograft. All of Spinal Implants and Biologics' sales are recorded in our Spine market sector.

Net sales in Breg increased \$1.4 million to \$23.3 million in the second quarter of 2009 compared to \$21.9 million for the same period last year, an increase of 7%. Breg's net sales represented 17% of total net sales during both second quarter of 2009 and 2008. The increase in Breg's net sales was primarily due to an 11% increase in sales of our Breg bracing products when compared to the same period in the prior year, primarily as a result of the sales of our new products which include spine bracing. Further, sales of our cold therapy products increased 5% over the same period in the prior year which is due to the recent launch of our new Kodiak® cold therapy products. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International decreased 10% to \$30.5 million in the second quarter of 2009 compared to \$34.0 million for the same period last year. International's net sales represented 22% and 26% of our total net sales in the second quarter of 2009 and 2008, respectively. The impact of foreign currency decreased International net sales by 16% or \$5.4 million, during the second quarter of 2009 as compared to the second quarter of 2008. On a constant currency basis, sales for Orthopedics and Vascular sectors increased 5% and 20%, respectively, in the second quarter of 2009 when compared to the prior year. Within Orthopedics, internal fixation, external fixation and stimulation increased 6%, 13% and 33%, respectively, on a constant currency basis, when compared with the same period last year. Sales in our Other distributed products, primarily the Laryngeal Mask, decreased 4% on a constant currency basis when compared to the same period in the prior year.

International Sales by Market Sector:

| (US\$ in thousands) | Net Sales for the Three Months Ended June 30, | | | | | |
|---------------------|--|------------------|--------------------|----------|--------------------------------|----------|
| | 2009 | 2008 | Reported Growth | | Constant Currency Growth | |
| Spine | \$ 565 | \$ 358 | 58 | % | 60 | % |
| Orthopedics | 19,133 | 21,559 | -11 | % | 5 | % |
| Sports Medicine | 1,118 | 1,288 | -13 | % | 4 | % |
| Vascular | 4,262 | 3,741 | 14 | % | 20 | % |
| Other | 5,466 | 7,063 | -23 | % | -4 | % |
| Total | \$ 30,544 | \$ 34,009 | -10 | % | 6 | % |

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Sales by Market Sector:

Sales of our Spine products increased to \$70.7 million in the second quarter of 2009 compared to \$62.7 in the second quarter of 2008. Sales of our Cervical-Stim® and Spinal-Stim® products increased 11% and 16%, respectively, in the second quarter of 2009 compared to 2008. In addition, sales of our Spinal Implants and Biologics products increased 12% over the same period in the prior year due to the introduction of new thoracolumbar products previously discussed as well as increased sales of biologics products which include sales of Trinity® and sales from the limited market release of our new Trinity® Evolution™ stem cell-based allograft. Spine product sales were 51% and 48% of our total net sales in the second quarters of both 2009 and 2008, respectively.

Sales of our Orthopedic products decreased \$0.7 million to \$32.6 million in the second quarter of 2009 compared to \$33.3 million for the same period last year. On a constant currency basis, sales increased 9% compared to the same period last year due to increased sales of our Physio Stim®, external fixation, and Biologics products. Orthopedic product sales were 24% of our total net sales in the second quarter of 2009 compared to 26% for the same period last year.

Sales of our Sports Medicine products increased 5% to \$24.5 million in the second quarter of 2009 compared to \$23.2 million for the same period last year. As discussed above, the increase of \$1.3 million is primarily due to sales of our Breg cold therapy and bracing products. Sports Medicine product sales were 18% of our total net sales in the second quarters of both 2009 and 2008.

Sales of our Vascular products, which consist of our A-V Impulse System®, increased 14% to \$4.3 million in the second quarter of 2009 compared to \$3.7 million for the same period last year. On a constant currency basis, sales increased 20% compared to the prior period. Vascular product sales were 3% of our total net sales in the second quarters of both 2009 and 2008.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our Woman's Care line, decreased 23% to \$5.5 million in the second quarter of 2009 when compared to \$7.1 million for the same period last year. On a constant currency basis, sales decreased 4% when compared to the second quarter of 2008. We distribute the Laryngeal Mask product in the United Kingdom and in Italy. In June 2010, we will transition out of the agreement to distribute the Laryngeal Mask product in the United Kingdom. Other product sales were 4% and 5% of our total net sales in the second quarters of 2009 and 2008, respectively.

Gross Profit – Our gross profit increased 6% to \$100.6 million in the second quarter of 2009, compared to \$95.0 million for the same period last year. Gross profit as a percent of net sales in the second quarter of 2009 was 73.2% compared to 73.0% for the same period last year. The increase in the gross profit is primarily due to the increased sales of higher margin stimulation products and Spinal Implants products. The gross margin in the second quarter of 2009 included the impact of a \$1.8 million increase in our inventory reserve, which related primarily to the supply of Trinity® allograft remaining on hand at the expiration of the company's distribution agreement on June 30, 2009.

Sales and Marketing Expense – Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$2.1 million, or 4%, to \$55.3 million in the second quarter of 2009 compared to \$53.2 million in the second quarter of 2008. As a percent of sales, sales and marketing expense was 40.2% and 40.9% in the second quarter of 2009 and 2008, respectively. This decrease is primarily due to the cost savings associated with reductions in the sales force and sales administration in our Spinal Implant and Biologics segment.

General and Administrative Expense – General and administrative expense increased \$2.4 million, or 13%, in the second quarter of 2009 to \$21.2 million compared to \$18.8 million in the second quarter of 2008. The increase is

primarily due to a restructuring charge to consolidate substantially all of Blackstone's current operations in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and US orthopedics business in the Dallas, TX area. General and administrative expense as a percent of sales was 15.4% in the second quarter of 2009 compared to 14.4% for the same period last year.

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Research and Development Expense – Research and development expense increased \$2.3 million in the second quarter of 2009 to \$8.9 million compared to \$6.6 million for the same period last year. This increase is primarily the result of our collaborative arrangement with Musculoskeletal Transplant Foundation (“MTF”). We incurred approximately \$2.1 million in expenses as the result of this collaboration for the three months ended June 30, 2009. As a percent of sales, research and development expense was 6.5% in the second quarter of 2009 compared to 5.1% for the same period last year. We expect to incur up to \$6.7 million of expense related to the MTF and IIS agreements in 2009; see Liquidity and Capital Resources for further detail.

Amortization of Intangible Assets – Amortization of intangible assets decreased \$3.2 million in the second quarter of 2009 to \$1.6 million compared to \$4.8 million for the same period last year. This decrease can be primarily attributed to the impairment of \$105.7 million of definite-lived intangible assets at Blackstone during the third quarter of 2008.

Interest Expense, net – Interest expense, net was \$5.8 million for the second quarter of 2009 compared to \$4.1 million for the same period last year. Included in interest expense, net for the second quarter of 2009 and 2008 was interest expense of \$5.8 and \$3.3 million, respectively, related to the senior secured term loan used to finance the Blackstone acquisition.

Unrealized Non-cash Gain on 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, the Company incurred an unrealized, non-cash loss of approximately \$8.0 million when it was determined that the Swap was no longer deemed highly effective. Therefore, cash flow accounting is no longer applied and mark-to-market adjustments are required to be reported in current earnings through the expiration of the swap in June 2011. For the three months ended June 30, 2009, the Company recorded an unrealized non-cash gain of \$1.0 million in other income (expense), net.

Other Income (Expense), net – Other income (expense), net reflected income of \$0.4 million for the second quarter of 2009 compared to income of \$0.6 million for the same period last year. Other expense increased by \$0.3 million in the second quarter of 2009 when compared with 2008. This was partially offset by an increase in net foreign exchange gains of \$0.1 million. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the US 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 effective tax rate, which represents a tax provision as a percentage of income before income taxes, was 35.9% and 27.9% during the second quarters of 2009 and 2008, respectively. The increase in the effective tax rate is primarily due to changes in the jurisdictional mix of earnings.

Net Income – Net income for the second quarter of 2009 was \$5.9 million, or \$0.35 per basic and diluted share, compared to net income of \$5.8 million, or \$0.34 per basic and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,107,084 and 17,090,217 during the second quarters of 2009 and 2008, respectively. The weighted average number of diluted common shares outstanding was 17,172,557 and 17,116,015 during the second quarters of 2009 and 2008, respectively.

Six Months Ended June 30, 2009 Compared to six Months Ended June 30, 2008

Net sales increased 3% to \$266.5 million for the six months of 2009 compared to \$258.1 million for the same period last year. The impact of foreign currency decreased sales by \$10.6 million during the first six months of 2009 when compared to the same period last year.

Sales by Business Segment:

Net sales in Domestic increased to \$103.4 million in the first six months of 2009 compared to \$91.3 million for the same period last year, an increase of 13%. Domestic's net sales represented 39% and 35% of total net sales during the first six months of 2009 and 2008, respectively. The increase in Domestic's net sales was partially the result of a 13% increase in sales in our Spine market sector, which was mainly driven by the increase in sales of our Spinal-Stim® and Cervical-Stim® products. The increase in Domestic's net sales was also attributable to the 15% increase in our Orthopedic market sector which included a 20% increase in sales of Physio-Stim® products as compared to the prior year period. Also attributing to the growth in the Orthopedic market is a \$1.5 million, or 98% growth, in sales of human cellular and tissue based products ("HCT/P products", often referred to as Biologics products) used in orthopedic applications when comparing these same two periods. Our biologics sales include sales of Trinity® and sales from the limited market release of our new Trinity® Evolution™ stem cell-based allograft.

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Domestic Sales by Market Sector:

| (US\$ in thousands) | Net Sales for the | | Growth | |
|---------------------|-------------------|-----------|--------|---|
| | 2009 | 2008 | | |
| Spine | \$ 77,425 | \$ 68,803 | 13 | % |
| Orthopedics | 26,007 | 22,529 | 15 | % |
| Total | \$ 103,432 | \$ 91,332 | 13 | % |

Net sales in Spinal Implants and Biologics increased \$2.7 million to \$58.5 million in the first six months of 2009 compared to \$55.8 million for the same period last year, an increase of 5%. Spinal Implants and Biologics' net sales represented 22% of total net sales during the first six months of 2009 and 2008. The increase in sales was primarily related to Biologics product sales which included sales from the limited market release of the Trinity® Evolution™ stem cell-based allograft during the second quarter of 2009. Sales of our thoracolumbar products increased 5% when compared to the same period last year due to the introduction of our new Firebird™ pedicle screw system. All of Spinal Implants and Biologics' sales are recorded in our Spine market sector.

Net sales in Breg increased \$2.5 million to \$46.5 million in the first six months of 2009 compared to \$44.0 million for the same period last year, an increase of 6%. Breg's net sales represented 17% of total net sales during the first six months of 2009 and 2008. The increase in Breg's net sales was primarily due to an 11% increase in sales of our Breg bracing products when compared to the same period in the prior year, primarily as a result of the sales of our new products which include spine bracing. Further, sales of our cold therapy products increased 6% over the same period in the prior year which is due to the recent launch of our new Kodiak® cold therapy products. These increases were partially offset by a decrease in sales of our pain therapy products as a result of the sale of operations related to our Pain Care® line of ambulatory infusion pumps during March 2008. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International decreased 13% to \$58.1 million in the first six months of 2009 compared to \$67.0 million for the same period last year. International's net sales represented 22% and 26% of our total net sales in the first six months of 2009 and 2008, respectively. The impact of foreign currency decreased International net sales by 15% or \$10.4 million, during the first six months of 2009 as compared to the same period last year. On a constant currency basis, both Orthopedics and Sports Medicine sales in our International segment increased 6% in the first six months of 2009 when compared to the prior year. Within Orthopedics, internal fixation, external fixation and stimulation increased 16%, 10% and 26%, respectively, on a constant currency basis, when compared with the same period last year. Sales in our Vascular sector, which consist of the A-V® Impulse System increased 1% on a constant currency basis, while sales from our Other distributed products, primarily the Laryngeal Mask, decreased 10% on a constant currency basis when compared to the prior year.

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International Sales by Market Sector:

| (US\$ in thousands) | Net Sales for the Six Months Ended June 30, | | Reported Growth | Constant Currency Growth | |
|---------------------|--|------------------|--------------------|--------------------------------|--|
| | 2009 | 2008 | | | |
| Spine | \$ 891 | \$ 612 | 46 % | 47 % | |
| Orthopedics | 36,212 | 40,566 | -11 % | 6 % | |
| Sports Medicine | 2,254 | 2,548 | -12 % | 6 % | |
| Vascular | 8,670 | 9,117 | -5 % | 1 % | |
| Other | 10,065 | 14,177 | -29 % | -10 % | |
| Total | \$ 58,092 | \$ 67,020 | -13 % | 2 % | |

Sales by Market Sector:

Sales of our Spine products increased to \$136.9 million in the first six months of 2009 compared to \$125.2 for the same period last year. Sales of our Cervical-Stim® and Spinal-Stim® products increased 11% and 14%, respectively, in the first six months of 2009 compared to 2008. In addition, sales of our Spinal Implants and Biologics products increased 5% over the same period in the prior year primarily due to the increase in sales in our Biologics products which included sales from the limited market release of the Trinity® Evolution™ stem cell-based allograft. Spine product sales were 52% and 49% of our total net sales in the first six months of 2009 and 2008, respectively.

Sales of our Orthopedic products decreased \$0.9 million to \$62.2 million in the first six months of 2009 compared to \$63.1 million for the same period last year. On a constant currency basis, sales increased 9% compared to the same period last year due to increased sales of our Physio Stim®, external fixation, and Biologics products. Orthopedic product sales were 23% and 24% of our total net sales in the first six months of 2009 and 2008, respectively.

Sales of our Sports Medicine products increased 5% to \$48.7 million in the first six months of 2009 compared to \$46.5 million for the same period last year. As discussed above, the increase of \$2.2 million is primarily due to sales of our Breg cold therapy and bracing products, offset by a decrease in our pain therapy products, which is principally attributable to the sale of operations relating to our Pain Care® line in March 2008. Sports Medicine product sales were 18% of our total net sales in the first six months of 2009 and 2008.

Sales of our Vascular products, which consist of our A-V Impulse System®, decreased 5% to \$8.7 million in the first six months of 2009 compared to \$9.1 million for the same period last year. On a constant currency basis, sales increased 1% compared to the prior period. Vascular product sales were 3% and 4% of our total net sales in the first six months of 2009 and 2008, respectively.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our Woman's Care line, decreased 29% to \$10.1 million in the first six months of 2009 when compared to \$14.2 million for the same period last year. On a constant currency basis, sales decreased 10% when compared to the first six months of 2008. We distribute the Laryngeal Mask product in the United Kingdom and in Italy. In June 2010, we will transition out of the agreement to distribute the Laryngeal Mask product in the United Kingdom. Other product sales were 4% and 5% of our total net sales in the first six months of 2009 and 2008, respectively.

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Gross Profit – Our gross profit increased 4% to \$196.8 million in the first six months of 2009, compared to \$188.8 million for the same period last year. Gross profit as a percent of net sales in the first six months of 2009 was 73.8% compared to 73.2% for the same period last year. The increase in the gross profit is primarily due to the increased sales of higher margin stimulation products and Spinal Implants products. The gross margin in the first six months of 2009 also included the impact of a \$1.8 million increase in our inventory reserve, which related primarily to the supply of Trinity® allograft remaining on hand at the expiration of the company’s distribution agreement on June 30, 2009.

Sales and Marketing Expense – Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$4.1 million, or 4%, to \$107.5 million in the first six months of 2009 compared to \$103.4 million for the same period last year. As a percent of sales, sales and marketing expense was 40.4% and 40.1% in the first six months of 2009 and 2008, respectively. The increase in sales and marketing expense as a percent of sales was due primarily to an increase in commission expenses reflecting the implementation of sales programs with new distributor partners. This increased investment in sales and marketing has facilitated the development of new customer relationships and increased sales, and has directly contributed to the improvement in the year-over-year operating profit margin in the Domestic segment.

General and Administrative Expense – General and administrative expense increased \$2.9 million, or 7%, in the first six months of 2009 to \$43.9 million compared to \$41.0 million for the same period last year. The increase is primarily due to a restructuring charge to consolidate substantially all of Blackstone’s current operations in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and US orthopedics business in the Dallas, TX area. In addition, the Company also incurred legal and other professional services associated with a proxy contest with one of the Company’s shareholders. The contest was settled in a special shareholder meeting on April 2, 2009. As a result, the Company does not anticipate incurring any expenses associated with this matter going forward. General and administrative expense as a percent of sales was 16.5% in the first six months of 2009 compared to 15.9% for the same period last year.

Research and Development Expense – Research and development expense increased \$5.0 million in the first six months of 2009 to \$18.0 million compared to \$13.0 million for the same period last year. This increase is primarily the result of two collaborative arrangements with Musculoskeletal Transplant Foundation (“MTF”) and Intelligent Implant Systems, LLC (“IIS”). We incurred approximately \$3.9 million and \$1.0 million in expenses as the result of our collaboration with MTF and IIS, respectively for the six months ended June 30, 2009. As a percent of sales, research and development expense was 6.7% in the first six months of 2009 compared to 5.0% for the same period last year. We expect to incur up to \$6.7 million of expense related to these agreements in 2009; see Liquidity and Capital Resources for further detail.

Amortization of Intangible Assets – Amortization of intangible assets decreased \$6.6 million in the first six months of 2009 to \$3.3 million compared to \$9.9 million for the same period last year. This decrease can be primarily attributed to the impairment of \$105.7 million of definite-lived intangible assets at Blackstone during the third quarter of 2008.

Gain on Sale of Pain Care® Operations – Gain on sale of Pain Care® operations was \$1.6 million in the first six months of 2008 and represented the gain on the sale of operations related to our Pain Care® line of ambulatory infusion pumps during March 2008. No such gain was recorded in the first six months of 2009.

Interest Expense, net – Interest expense, net was \$11.9 million for the first six months of 2009 compared to \$9.5 million for the same period last year. Included in interest expense, net for the first six months of 2009 and 2008 was interest expense of \$11.8 million and \$8.3 million related to the senior secured term loan used to finance the Blackstone acquisition.

Unrealized Non-cash Gain on 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, the Company incurred an unrealized, non-cash loss of approximately \$8.0 million when it was determined that the Swap was no longer deemed highly effective. Therefore, cash flow accounting is no longer applied and mark-to-market adjustments are required to be reported in current earnings through the expiration of the swap in June 2011. For the six months ended June 30, 2009, the Company recorded an unrealized non-cash gain of \$1.3 million in other income (expense), net.

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Other Income (Expense), net – Other income (expense), net was income of \$0.1 million for the six months of 2009 compared to income of \$1.1 million for the same period last year. The decrease can be mainly attributed to the effect of foreign exchange. During the first six months of 2009, we recorded foreign exchange gains of \$0.6 million compared with foreign exchange gains of \$1.2 million for the same period last year. The decrease is principally as a result of a rapid strengthening of the US Dollar against various foreign currencies including the Euro, Pound, Peso and Brazilian Real. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the US 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 effective tax rate, which represents a tax provision as a percentage of income before income taxes, was 35.0% and 36.2% during the first six months of 2009 and 2008, respectively. The effective tax rate for the first six months of 2008 included an unfavorable discrete item resulting from the sale of our Pain Care® operations. Excluding this discrete item, the effective rate for the second quarter of 2008 was 29.9%. The increase in the effective tax rate (excluding the impact of the sale of our Pain Care® operations) is primarily due to changes in the jurisdictional mix of earnings.

Net Income – Net income for the first six months of 2009 was \$8.8 million, or \$0.52 per basic and diluted share, compared to net income of \$9.4 million, or \$0.55 per basic and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,105,323 and 17,088,735 during the first six months of 2009 and 2008, respectively. The weighted average number of diluted common shares outstanding was 17,139,789 and 17,240,004 during the first six months of 2009 and 2008, respectively.

Liquidity and Capital Resources

Cash and cash equivalents at June 30, 2009 were \$21.5 million, of which \$15.6 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$25.6 million at December 31, 2008, of which \$11.0 million was restricted.

Net cash provided by operating activities was \$17.0 million for the six months ended June 30, 2009 compared to \$2.3 million for the same period last year. Net cash provided by operating activities is comprised of net income, non-cash items (including depreciation and amortization, share-based compensation, provision for doubtful accounts, provision for inventory obsolescence and gain on the sale of Pain Care® operations) and changes in working capital, including changes in restricted cash. Net income decreased \$0.6 million to \$8.8 million for the six months ended June 30, 2009 from net income of \$9.4 million for the comparable period in the prior year. Non-cash items for the six months ended June 30, 2009 increased \$1.5 million compared to the same period last year primarily as a result of an increase in the inventory obsolescence reserve and depreciation expense, offset by lower amortization as a result of the impairment of \$105.7 million of definite-lived intangible assets at Blackstone during the third quarter of 2008. Working capital accounts consumed \$15.9 million of cash in the six months ended June 30, 2009 compared to \$29.7 million for the same period last year. The principal change in working capital can be mainly attributable to inventory due to improved inventory purchasing at our Spinal Implants and Biologics business. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 79 days at June 30, 2009 compared to 83 days at June 30, 2008 and inventory turns of 1.6 times at June 30, 2009 compared to 1.2 times at June 30, 2008. Also included in the uses of working capital during the six months ended of 2009 were \$3.6 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 \$9.2 million during the six months ended June 30, 2009 compared to \$6.2 million provided by investing activities during the same period last year. During the first half of 2009 and 2008, we invested \$9.2 million and \$12.2 million in capital expenditures, respectively. During the first quarter of 2008, we sold

the operations of our Pain Care® line of ambulatory infusion pumps for net proceeds of \$6.0 million.

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Net cash used in financing activities was \$16.6 million for the six months ended June 30, 2009 compared to \$4.5 million for the same period last year. During the six months ended June 30, 2009, we repaid approximately \$16.6 million against the principal on our senior secured term loan compared to \$5.4 million during the six months ended June 30, 2008. During the first half of 2009, we used approximately \$1.1 million to purchase an additional 32% minority interest in our Breg distributor in Germany. During the six months ended June 30, 2008, we received proceeds of \$1.9 million from the issuance of 52,397 shares of our common stock upon the exercise of stock options.

On September 22, 2006 the Company's wholly-owned US holding company subsidiary, Orthofix Holdings, Inc. ("Orthofix Holdings"), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. Certain terms of the senior secured credit facility were amended in September 29, 2008. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million and (2) a six-year revolving credit facility of \$45.0 million. As of June 30, 2009, the Company had no amounts outstanding under the revolving credit facility and \$264.1 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of the London Inter-Bank Offered Rate ("LIBOR") plus a margin, with a LIBOR floor of 3.0% or prime rate plus a margin. Currently, the term loan is a \$150.0 million LIBOR loan plus a margin of 4.50% and \$114.1 million prime rate loan plus a margin of 3.50%.

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. The amount outstanding under the Swap as of June 30, 2009 was \$150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of June 30, 2009, the effective interest rate on the debt related to the Swap was 10.0%. Our overall effective interest rate, including the impact of the Swap as of June 30, 2009 on our senior secured debt was 8.6%.

The credit agreement contains certain financial covenants, including a fixed charge coverage ratio and a leverage ratio applicable to Orthofix and its 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. Management believes the Company was in compliance with these financial covenants as measured at June 30, 2009. As defined in the senior secured credit facility, our leverage ratio requires us to not exceed 4.00 and our fixed charge ratio requires us to be greater than or equal to 1.30. At June 30, 2009, our leverage and fixed charge ratios were 3.60 and 1.42, respectively. The Company further believes that it should be able to meet these financial covenants in future fiscal quarters, however, there can be no assurance that it 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.

Each of the domestic subsidiaries of the Company (which includes Orthofix Inc., Breg Inc., and Blackstone) and Colgate Medical Limited and Victory Medical Limited (wholly-owned financing subsidiaries of the Company) has guaranteed the obligations of Orthofix Holdings under the senior secured credit facility. The obligations of the subsidiaries under their guarantees are secured by the pledges of their respective assets.

At June 30, 2009, we had outstanding borrowings of \$3.1 million and unused available lines of credit of approximately 5.1 million Euro (\$7.2 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.

On July 24, 2008, we entered into an agreement with Musculoskeletal Transplant Foundation ("MTF") to collaborate on the development and commercialization of a new stem cell-based bone growth biologic matrix. Under the terms of the agreement, we have invested \$10.0 million to develop the new stem cell-based bone growth biologic matrix that

provides the beneficial properties of an autograft in spinal and orthopedic surgeries. With the development process now complete, the Company and MTF operate under the terms of a separate commercialization agreement. Under the terms of this 10-year agreement, MTF sources the tissue, processes it to create the bone growth matrix, and packages and delivers it in accordance with orders received directly from customers and from the Company. The Company has exclusive global marketing rights for the new allograft and receives a marketing fee from MTF based on total sales. We account for this collaborative arrangement under guidance included in Emerging Issues Task Force Issue No. 07-1 "Accounting for Collaborative Arrangements." The new matrix was launched in the US during the second quarter of 2009. A total of \$3.9 million of expenses incurred under the terms of the agreement are included in research and development expense in the six months ended June 30, 2009.

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As previously announced in 2008, we entered into an agreement with Intelligent Implant Systems (“IIS”) for the acquisition and development of a next-generation pedicle screw system for our spinal implants division. Under the agreement we purchased \$2.5 million of intellectual property and related technology. In addition, during the first half of 2009, IIS met their first development milestone and under the terms of the agreement the Company paid IIS \$1.0 million. The Company has recorded this as research and development expense in the six months ended June 30, 2009. IIS will continue to perform research and development functions related to the technology and under the agreement we will pay IIS an additional amount up to \$3.5 million for research and development performance milestones.

We believe that current cash balances together with projected cash flows from operating activities, the unused availability of the \$45.0 million revolving credit facility, the available Italian line of credit, and our debt capacity are sufficient to cover anticipated working capital and capital expenditure needs including research and development costs and research and development projects formerly mentioned, over the near term.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations, and the cost of financing and yields on cash and short-term investments. We use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of June 30, 2009, we had a currency swap in place to minimize foreign currency exchange risk related to a 38.3 million Euro intercompany note.

We are exposed to interest rate risk in connection with our senior secured term loan and borrowings under our revolving credit facility, which bear interest at floating rates based on LIBOR or the prime rate 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. We had an interest rate swap in place as of June 30, 2009 to minimize interest rate risk related to our LIBOR-based borrowings.

As of June 30, 2009, we had \$264.1 million of variable rate term debt represented by borrowings under our senior secured term loan at a floating interest rate of LIBOR plus a margin, with a LIBOR floor of 3.0% or the prime rate plus a margin. Currently, the term loan is a \$150.0 million LIBOR loan plus a margin of 4.50% and a \$114.1 million prime rate loan plus a margin of 3.5%, which are adjusted based upon the credit rating of the Company and its subsidiaries. In June 2008, we entered into a Swap with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of June 30, 2009 was \$150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of June 30, 2009 the effective interest rate on the debt related to the Swap was 10.0%. Our overall effective interest rate, including the impact of the Swap, as of June 30, 2009 on our senior secured debt was 8.6%. Based on the balance outstanding under the senior secured term loan combined with the Swap as of June 30, 2009, an immediate change of one percentage point in the applicable interest rate on the variable rate debt would cause a change in interest expense of approximately \$1.3 million on an annual basis.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the US 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 US Dollars. We are subject to transactional currency exposures when foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. As of June 30, 2009, we had an un-hedged intercompany receivable denominated in Euro for approximately 31.2 million. We recorded a foreign currency gain during the first half of 2009 of \$0.2 million, which resulted from the strengthening of the Euro against the US dollar during the period.

We also are subject to currency exposure from translating the results of our global operations into the US dollar at exchange rates that have fluctuated from the beginning of the period. The US dollar equivalent of international sales denominated in foreign currencies was unfavorably impacted during the six months ended June 30, 2009 by foreign currency exchange rate fluctuations with the strengthening of the US dollar against the local foreign currency during this period. The US dollar equivalent of the related costs denominated in these foreign currencies was favorably impacted during this period. During the six months ended June 30, 2008, the US dollar equivalent of international sales denominated in foreign currencies was favorably impacted by foreign currency exchange rate fluctuations with the weakening of the US dollar against the local foreign currency during this period. The US dollar equivalent of the related costs denominated in these foreign currencies was unfavorably impacted 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 Chief Executive Officer and our Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a - 15(e) or 15d - 15 (e)) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

On July 1, 2009, we implemented an Enterprise Resource Planning (“ERP”) system at our Spinal Implants and Biologics division. The ERP system, developed by Oracle, is expected to improve and enhance internal controls over financial reporting. This ERP system materially changes how transactions are processed within this division.

Except for the conversion to the ERP system, there have not been any changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2009 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 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 us 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.

On or about January 7, 2008, the Company received a federal grand jury subpoena from the United States 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 for the Company received a HIPAA subpoena issued by the US 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, as well as the January 7, 2008 federal grand jury subpoena. On or about June 15, 2009, Orthofix, Inc., and Blackstone, executed an agreement with the United States Attorney's Office for the District of Massachusetts (the "Tolling Agreement") extending an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate. The Tolling Agreement extended the period tolling the statute of limitations to include the period from December 1, 2008 through and including December 31, 2009.

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 US 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 US Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. On November 21, 2008, the US 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 United States Attorney's Office for the District of Massachusetts. 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 US 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 us resulting from this matter.

On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the United States 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 Company believes that the CID seeks documents concerning Blackstone's financial relationships with certain physicians and related matters for the period from March 2004 through the date of issuance of the CID. 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 us resulting from the USAO-Nevada subpoena, the Massachusetts CID and the Ohio AG subpoena.

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By order entered on January 4, 2007, the United States 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 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 us 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.

The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund and there can be no assurance that losses to us from these matters will not exceed the amount of the escrow account. As of June 30, 2009 and December 31, 2008, included in Prepaid expenses and other current assets is approximately \$11.5 million and \$8.3 million of escrow receivable balances related to the Blackstone matters described above, respectively.

In addition to the foregoing claims, the Company has submitted claims for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for losses that have 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 Blackstone's 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.

On or about April 10, 2009, the Company received a HIPAA subpoena ("HIPAA subpoena") issued by the US Attorney's Office for the District of Massachusetts. The subpoena seeks documents for the period January 1, 1995 through the date of the subpoena. The Company believes that the subpoena concerns the classification and marketing of its bone growth stimulators and related matters. The Company intends to cooperate with the government's requests. The Company is unable to predict what actions, if any, might be taken by the government or what impact, if any, the outcome of this matter might have on the Company's consolidated financial position, results of operations or cash flows.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the US District Court for the District of Massachusetts against Orthofix, Inc., the Company, 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 amended 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 amended 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. To the best of the Company's knowledge, the plaintiff has not served either Orthofix, Inc. or the Company. If served, the Company intends to defend vigorously against this lawsuit.

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 US District Court for the District of Massachusetts against the Company. This complaint has been consolidated with the complaint described in the immediately preceding paragraph, and was unsealed on June 30, 2009. The amended complaint alleges violations of the False Claims Act, fraudulent billing, illegal kickbacks, wrongful termination, conspiracy, and violations of the Sherman Anti-trust Act based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products, provided physicians kickbacks in the form of free units, referral fees, and fitting fees, and that the defendant and its competitors discussed together strategies to encourage higher government pricing for the products. The amended complaint also alleges that TRICARE has been reimbursing for the Company's Cervical Stim product without approval to do so. To the best of the Company's knowledge the plaintiff has not served the Company. If served, the Company intends to defend vigorously against this lawsuit.

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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 US patents and that Blackstone's making, selling, offering for sale, and using its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products within the United States 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 Company's 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 us 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.

The Company cannot predict the outcome of any proceedings 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 our consolidated financial position, results of operations, or cash flows.

In addition to the foregoing, in the normal course of our business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies.

Item 1A. Risk Factors

There have been no material changes to our risk factors from the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

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Item 4. Submission of Matters to a Vote of Security Holders

A Special General Meeting of Shareholders of the Company took place on April 2, 2009. The results of the Special General Meeting were previously reported in Part II, Item 4, of the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2009.

The Annual General Meeting of Shareholders of the Company was held on June 30, 2009. The total number of common shares eligible to vote as of the record date, May 6, 2009, was 17,103,142 and pursuant to the Company's Articles of Association, 8,551,571 shares were required to be present or represented at the meeting to constitute a quorum. The total number of common shares present or represented at the meeting was 15,970,686, and a quorum therefore existed.

At the Annual General Meeting:

1. The following persons were elected by a plurality of the votes cast at the meeting as Directors of the Company for a one year term expiring at the Annual General Meeting in 2010:

| Name | Votes | |
|------------------------|------------|-----------|
| | Votes For | Withheld |
| Jerry C. Benjamin | 15,022,668 | 948,018 |
| Charles W. Federico | 14,696,948 | 1,271,738 |
| James F. Gero | 14,937,477 | 1,033,209 |
| Guy J. Jordan | 15,463,368 | 507,318 |
| Thomas J. Kester | 15,461,868 | 508,818 |
| Alan W. Milinazzo | 15,050,557 | 920,129 |
| Maria Sainz | 15,467,116 | 503,570 |
| Walter P. Von Wartburg | 14,594,786 | 1,375,900 |
| Kenneth R. Weisshaar | 15,461,616 | 509,070 |

2. A further Amendment and Restatement to the Company's Amended and Restated 2004 Long-Term Incentive Plan was not approved by a vote of 10,688,412 against, 3,971,584 in favor and 337,410 abstaining; and
3. Amendment No. 1 to the Company's Amended and Restated Stock Purchase Plan was approved by a vote of 13,759,688 in favor 894,237 against, and 343,481 abstaining; and
4. A proposal to approve the material terms for the payment of certain incentive compensation to the Company's most highly compensated executive officers under the Company's annual incentive program was approved by a vote of 14,185,107 in favor, 478,047 against and 334,252 abstaining; and
5. The Company's balance sheet and income statement at and for the year ended December 31, 2008 were approved by a vote of 15,067,592 in favor, 19,270 against and 883,824 abstaining; and
6. The selection of Ernst & Young LLP to act as the independent registered public accounting firm for the Company and its subsidiaries for the fiscal year ending December 31, 2009 was ratified by a vote of 15,069,538 in favor, 565,595 against and 335,553 abstaining.

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Item 6. Exhibits

| (a) | Exhibits |
|----------------|--|
| Exhibit Number | Description |
| 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). |
| <u>10.1*</u> | Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended. |
| <u>10.2*</u> | Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan. |
| 10.3 | 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). |
| 10.4 | 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). |
| 10.5 | 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). |
| 10.6 | 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). |
| 10.7 | 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). |
| 10.8 | Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (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). |
| 10.9 | 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). |

10.10 Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company's current report on Form 8-K filed January 7, 2009, and incorporated herein by reference).

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- 10.11 Acquisition Agreement dated as of November 20, 2003, among Orthofix International N.V., Trevor Acquisition, Inc., Breg, Inc. and Bradley R. Mason, as shareholders' representative (filed as an exhibit to the Company's current report on Form 8-K filed January 8, 2004 and incorporated herein by reference).
- 10.12 Amended and Restated Voting and Subscription Agreement dated as of December 22, 2003, among Orthofix International N.V. and the significant shareholders of Breg, Inc. identified on the signature pages thereto (filed as an exhibit to the Company's current report on Form 8-K filed on January 8, 2004 and incorporated herein by reference).
- 10.13 Amendment to Employment Agreement dated December 29, 2005 between Orthofix Inc. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed December 30, 2005 and incorporated herein by reference).
- 10.14 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).
- 10.15 Settlement Agreement dated February 23, 2006, between Intavent Orthofix Limited, a wholly-owned subsidiary of Orthofix International N.V. and Galvin Mould (filed as an exhibit to the Company's annual report on Form 8-K filed on April 17, 2006 and incorporated herein by reference).
- 10.16 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).
- 10.17 Credit Agreement, dated as of September 22, 2006, among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, the several banks and other financial institutions as may from time to time become parties thereunder, and Wachovia Bank, National Association (filed as an exhibit to the Company's current report on Form 8-K filed September 27, 2006 and incorporated herein by reference).
- 10.18 First Amendment to Credit Agreement, dated September 29, 2008, by and among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, and Wachovia Bank, National Association, as administrative agent on behalf of the Lenders under the Credit Agreement (filed as an exhibit to the Company's current report on Form 8-K filed September 29, 2008 and incorporated herein by reference).
- 10.19 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).

10.20 Employment Agreement, dated as of September 22, 2006, between Blackstone Medical, Inc. and Matthew V. Lyons (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2006, as amended, and incorporated herein by reference).

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| 10.21 | Amended and Restated Employment Agreement dated December 6, 2007 between Orthofix Inc. and Timothy M. Adams (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). |
| 10.22 | Nonqualified Stock Option Agreement between Timothy M. Adams and Orthofix International N.V. dated November 19, 2007 (filed as an exhibit to the Company's current report on Form 8-K filed November 21, 2007 and incorporated herein by reference). |
| 10.23 | Employment Agreement between Orthofix Inc. and Scott Dodson, dated as of December 10, 2007 (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). |
| 10.24 | Employment Agreement between Orthofix Inc. and Michael Simpson, dated as of December 6, 2007 (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). |
| 10.25 | Description of Director Fee Policy (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2009 and incorporated herein by reference). |
| 10.26 | Summary of Orthofix International N.V. Annual Incentive Program (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2009 and incorporated herein by reference). |
| 10.27 | Employment Agreement between Orthofix Inc. and Thomas Hein dated as of April 11, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference). |
| 10.28 | Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan, dated April 11, 2008, between Orthofix International N.V. and Thomas Hein (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference). |
| 10.29 | Summary of Consulting Arrangement between Orthofix International N.V. and Peter Hewett (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference). |
| 10.30 | Employment Agreement between Orthofix Inc. and Denise E. Pedulla dated as of June 9, 2008 (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). |
| 10.31 | Form of 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).

10.32+ Letter Agreement between Orthofix Inc. and Oliver Burckhardt dated August 28, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference).

10.33 Notice of Termination from Orthofix Inc. to Oliver Burckhardt dated August 27, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference).

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| 10.34 | 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). |
| 10.35 | 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). |
| 10.36 | 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). |
| 10.37 | 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). |
| 10.38 | 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). |
| 10.39 | 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). |
| 10.40 | Form of Amendment to Stock Option Agreements (for Alan W. Milinazzo, Robert S. Vaters, Bradley R. Mason, 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). |
| <u>31.1*</u> | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer. |
| <u>31.2*</u> | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer. |
| <u>32.1*</u> | Section 1350 Certification of Chief Executive Officer. |
| <u>32.2*</u> | 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 the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORTHOFIX INTERNATIONAL N.V.

Date: July 31, 2009

By:

/s/ Alan W. Milinazzo

Name: Alan W. Milinazzo

Title: Chief Executive Officer and
President

Date: July 31, 2009

By:

/s/ Robert S. Vaters

Name: Robert S. Vaters

Title: Executive Vice President and Chief
Financial Officer