

ORTHOFIX INTERNATIONAL N V
Form 10-Q
April 29, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2010

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
Curacao
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 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 April 23, 2010, 17,613,813 shares of common stock were issued and outstanding.

Table of Contents

| | | |
|------------------------------|--|----|
| PART I FINANCIAL INFORMATION | | |
| Item 1. | <u>Condensed Consolidated Financial Statements</u> | 3 |
| Item 2. | <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> | 20 |
| Item 3. | <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 30 |
| Item 4. | <u>Controls and Procedures</u> | 31 |
| PART II OTHER INFORMATION | | |
| Item 1. | <u>Legal Proceedings</u> | 32 |
| Item 1A. | <u>Risk Factors</u> | 35 |
| Item 6. | <u>Exhibits</u> | 36 |
| <u>SIGNATURES</u> | | 41 |

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 or contribute to such differences may include, but are not limited to, risks relating to the expected sales of its products, including recently launched products, unanticipated expenditures, changing relationships with customers, suppliers, strategic partners and lenders, changes to and the interpretation of governmental regulations, ongoing litigation matters and governmental investigations of our businesses which could result in civil or criminal liability or findings of violations of law (as further described in the “Legal Proceedings” sections of this Form 10-Q), risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry, credit markets and the economy, corporate development and market development activities, including acquisitions or divestitures, unexpected costs or operating unit performance related to recent acquisitions, and other risks described in Part II, Item 1A under the heading “Risk Factors” in this Form 10-Q.

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

ORTHOFIX INTERNATIONAL N.V.
CONDENSED CONSOLIDATED BALANCE SHEETS

| (U.S. Dollars, in thousands except share data) | March 31, 2010 (unaudited) | December 31, 2009 |
|---|----------------------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 18,759 | \$ 13,328 |
| Restricted cash | 15,963 | 11,630 |
| Trade accounts receivable, less allowance for doubtful accounts of \$6,754 and \$7,205 at March 31, 2010 and December 31, 2009, respectively | 134,487 | 129,777 |
| Inventories, net | 88,451 | 94,624 |
| Deferred income taxes | 21,134 | 20,286 |
| Prepaid expenses | 6,031 | 4,868 |
| Other current assets | 26,477 | 24,981 |
| Total current assets | 311,302 | 299,494 |
| Investments, at cost | 345 | 345 |
| Property, plant and equipment, net | 37,414 | 38,694 |
| Patents and other intangible assets, net | 45,619 | 47,628 |
| Goodwill | 176,022 | 185,175 |
| Deferred taxes and other long-term assets | 19,124 | 19,137 |
| Total assets | \$ 589,826 | \$ 590,473 |
| Liabilities and shareholders' equity | | |
| Current liabilities: | | |
| Bank borrowings | \$ 2,049 | \$ 2,209 |
| Current portion of long-term debt | 3,330 | 3,332 |
| Trade accounts payable | 21,372 | 23,302 |
| Other current liabilities | 59,723 | 59,210 |
| Total current liabilities | 86,474 | 88,053 |
| Long-term debt | 229,305 | 249,132 |
| Deferred income taxes | 6,348 | 6,115 |
| Other long-term liabilities | 4,026 | 6,904 |
| Total liabilities | 326,153 | 350,204 |
| Contingencies (Note 19) | | |
| Shareholders' equity: | | |
| Common shares \$0.10 par value; 50,000,000 shares authorized; 17,547,037 and 17,141,710 issued and outstanding as of March 31, 2010 and December 31, 2009, respectively | 1,755 | 1,714 |
| Additional paid-in capital | 186,458 | 177,246 |
| Retained earnings | 71,612 | 54,119 |
| Accumulated other comprehensive income | 3,848 | 7,190 |
| Total shareholders' equity | 263,673 | 240,269 |
| Total liabilities and shareholders' equity | \$ 589,826 | \$ 590,473 |

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.
 CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
 FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

| (Unaudited, U.S. Dollars, in thousands except share and per share data) | Three Months Ended March 31, | |
|---|---------------------------------|------------|
| | 2010 | 2009 |
| Net sales | \$ 138,823 | \$ 128,974 |
| Cost of sales | 32,694 | 32,806 |
| Gross profit | 106,129 | 96,168 |
| Operating expenses | | |
| Sales and marketing | 56,290 | 52,264 |
| General and administrative | 21,470 | 22,684 |
| Research and development | 7,528 | 9,087 |
| Amortization of intangible assets | 1,447 | 1,633 |
| Gain on sale of vascular operations | (12,551) | - |
| | 74,184 | 85,668 |
| Operating income | 31,945 | 10,500 |
| Other income (expense), net | | |
| Interest expense, net | (5,846) | (6,117) |
| Unrealized non-cash gain on interest rate swap | 345 | 239 |
| Other expense, net | (330) | (323) |
| | (5,831) | (6,201) |
| Income before income taxes | 26,114 | 4,299 |
| Income tax expense | (8,622) | (1,420) |
| Net income | \$ 17,492 | \$ 2,879 |
| Net income per common share - basic | \$ 1.00 | \$ 0.17 |
| Net income per common share - diluted | \$ 0.99 | \$ 0.17 |
| Weighted average number of common shares - basic | 17,489,315 | 17,103,543 |
| Weighted average number of common shares - diluted | 17,757,099 | 17,121,571 |

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
 FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

| (Unaudited, U.S. Dollars, in thousands) | 2010 | 2009 |
|---|-----------|-----------|
| Cash flows from operating activities: | | |
| Net income | \$ 17,492 | \$ 2,879 |
| Adjustments to reconcile net income to net cash (used in) provided by operating activities: | | |
| Depreciation and amortization | 5,398 | 5,217 |
| Amortization of debt costs | 54 | 49 |
| Provision for doubtful accounts | 1,716 | 1,648 |
| Deferred taxes | (1,417) | (93) |
| Share-based compensation | 3,013 | 2,824 |
| Provision for inventory obsolescence | 2,868 | 1,755 |
| Change in fair value of interest rate swap | (345) | (239) |
| Gain on sale of vascular operations | (12,551) | - |
| Other | 489 | 1,503 |
| Change in operating assets and liabilities: | | |
| Restricted cash | (4,353) | (191) |
| Accounts receivable | (8,407) | (1,686) |
| Inventories | (66) | (4,060) |
| Prepaid expenses and other current assets | (2,882) | 79 |
| Accounts payable | (1,313) | 1,090 |
| Current liabilities | (108) | 325 |
| Net cash (used in) provided by operating activities | (412) | 11,100 |
| Cash flows from investing activities: | | |
| Capital expenditures | (4,353) | (3,536) |
| Net proceeds from sale of assets, principally vascular operations | 24,193 | - |
| Net cash provided by (used in) investing activities | 19,840 | (3,536) |
| Cash flows from financing activities: | | |
| Repayments of long-term debt | (19,829) | (12,804) |
| Repayments of bank borrowings, net | (38) | (1,128) |
| Proceeds from issuance of common stock | 4,613 | - |
| Cash payment for purchase of minority interest in subsidiary | - | (1,143) |
| Tax benefit on non-qualified stock options | 1,628 | - |
| Net cash used in financing activities | (13,626) | (15,075) |
| Effect of exchange rate changes on cash | (371) | (266) |
| Net increase (decrease) in cash and cash equivalents | 5,431 | (7,777) |
| Cash and cash equivalents at the beginning of the year | 13,328 | 14,594 |
| Cash and cash equivalents at the end of the period | \$ 18,759 | \$ 6,817 |

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

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 Orthopedics products market. The Company is comprised of four reportable segments: Domestic, Spinal Implants and Biologics (formerly referred to as “Blackstone”), Breg and International. See Note 12 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 (“U.S.”) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures, normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S., have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. The balance sheet at December 31, 2009 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. For further information, refer to the Consolidated Financial Statements and Notes thereto of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

NOTE 3: SHARE-BASED COMPENSATION

All share-based compensation costs are measured at the grant date, based on the estimated fair value of the award, and are recognized as expense in the 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 months ended March 31, 2010 and 2009:

| (US\$ in thousands) | Three Months Ended March 31, | |
|----------------------------|---------------------------------|----------|
| | 2010 | 2009 |
| Cost of sales | \$ 98 | \$ 66 |
| Sales and marketing | 980 | 504 |
| General and administrative | 1,823 | 2,137 |
| Research and development | 112 | 117 |
| Total | \$ 3,013 | \$ 2,824 |

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

NOTE 4: RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform to the 2010 presentation. The reclassifications have no effect on previously reported net income or shareholders' equity.

Table of Contents

NOTE 5: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 products, field inventory and consignment inventory includes the cost of materials, labor and production. Field inventory represents immediately saleable finished products inventory that is in the possession of the Company's direct sales representatives and independent distributors.

Inventories were as follows:

| (US\$ in thousands) | March 31, 2010 | December 31, 2009 |
|-------------------------------|-------------------|----------------------|
| Raw materials | \$10,252 | \$ 11,777 |
| Work-in-process | 7,150 | 6,687 |
| Finished products | 55,114 | 59,812 |
| Field inventory | 33,804 | 31,970 |
| Consignment inventory | 8,213 | 8,259 |
| | 114,533 | 118,505 |
| Less reserve for obsolescence | (26,082) | (23,881) |
| | \$88,451 | \$ 94,624 |

NOTE 6: GOODWILL

The changes in the carrying value of goodwill by reportable segment for the period ended March 31, 2010 are as follows:

| (US\$ in thousands) | Domestic | Spinal Implants and Biologics | Breg | International | Total |
|----------------------|----------|--|----------|---------------|-----------|
| At December 31, 2009 | \$31,793 | \$9,367 | \$99,295 | \$ 44,720 | \$185,175 |
| Disposal(1) | - | - | - | (7,031) | (7,031) |
| Foreign currency | - | - | - | (2,122) | (2,122) |
| At March 31, 2010 | \$31,793 | \$9,367 | \$99,295 | \$ 35,567 | \$176,022 |

(1) Sale of the vascular operations – see Note 18 “Sale of Vascular Operations.”

NOTE 7: PATENTS AND OTHER INTANGIBLE ASSETS

| (US\$ in thousands) | March 31, 2010 | December 31, 2009 |
|---|-------------------|----------------------|
| Cost | | |
| Patents and developed technologies | \$27,827 | \$ 27,961 |
| Trademarks – definite lived (subject to amortization) | 120 | 119 |
| Trademarks – indefinite lived (not subject to amortization) | 23,534 | 23,542 |
| Distribution networks | 44,586 | 44,586 |
| | 96,067 | 96,208 |
| Accumulated amortization | | |
| Patents and developed technologies | (18,510) | (17,499) |

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

| | | |
|---|-----------|-----------|
| Trademarks – definite lived (subject to amortization) | (108) | (107) |
| Distribution networks | (31,830) | (30,974) |
| Patents and other intangible assets, net | \$45,619 | \$ 47,628 |

7

Table of Contents

Amortization expense for intangible assets is estimated to be approximately \$4.5 million for the remainder of 2010 and \$5.9 million, \$4.7 million, \$1.6 million, \$1.6 million, \$1.1 million and \$2.7 million for the periods ending December 31, 2011, 2012, 2013, 2014, 2015 and 2016 and thereafter, respectively.

NOTE 8:

BANK BORROWINGS

| (US\$ in thousands) | March 31, 2010 | December 31, 2009 |
|---------------------------------|-------------------|----------------------|
| Borrowings under line of credit | \$2,049 | \$ 2,209 |

The weighted average interest rates on borrowings under lines of credit as of March 31, 2010 and December 31, 2009 were 3.66% and 5.15%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 5.8 million Euros (\$7.8 million) and 5.8 million Euros (\$8.2 million) at March 31, 2010 and December 31, 2009, respectively, in its Italian line of credit. This line of credit provides 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 9:

LONG-TERM DEBT

| (US\$ in thousands) | March 31, 2010 | December 31, 2009 |
|-----------------------|-------------------|----------------------|
| Long-term obligations | \$232,575 | \$ 252,400 |
| Other loans | 60 | 64 |
| | 232,635 | 252,464 |
| Less current portion | (3,330) | (3,332) |
| | \$229,305 | \$ 249,132 |

On September 22, 2006 the Company's wholly-owned U.S. 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 on September 29, 2008 and February 24, 2010. 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 March 31, 2010, the Company had \$0.3 million of letters of credit outstanding under the revolving credit facility and \$232.6 million outstanding under the term loan facility. Obligations under the senior secured credit facility can 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. As of March 31, 2010, the entire term loan obligation of \$232.6 million is at the prime rate 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 16), as of March 31, 2010 and December 31, 2009 were 9.0% and 8.8%, respectively.

The Company made a mandatory payment on its principal balance amounting to \$19.0 million on March 31, 2010. This principal payment represented all of the preliminary net proceeds the Company received on the sale of its vascular operations on March 8, 2010 (see Note 18).

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.

Table of Contents

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 March 31, 2010 is \$170.9 million compared to \$143.0 million at December 31, 2009. 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 March 31, 2010 is \$16.0 million compared to \$11.6 million at December 31, 2009.

NOTE 10: COMMON SHARES

During the three months period ended March 31, 2010, there were 405,327 shares of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

NOTE 11: COMPREHENSIVE INCOME (LOSS)

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and the effective portion of the gain (loss) from the Company's cross-currency swap which is designated and accounted for as a cash flow hedge (refer to Note 16). The components of and changes in accumulated other comprehensive income are as follows:

| (US\$ in thousands) | Foreign Currency Translation Adjustments | Fair Value of Cross -Currency Swap | Accumulated Other Comprehensive Income/(Loss) |
|---|---|---|--|
| Balance at December 31, 2009 | \$ 6,795 | \$395 | \$ 7,190 |
| Unrealized loss on cross-currency swap, net of tax of \$(172) | - | (445) | (445) |
| Foreign currency translation adjustment(1) | (2,897) | - | (2,897) |
| Balance at March 31, 2010 | \$ 3,898 | \$(50) | \$ 3,848 |

(1)As the cash remains permanently invested in the foreign subsidiaries, no deferred taxes are recognized on the related foreign currency translation adjustment.

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

| (US\$ in thousands) | Three Months Ended March 31, | |
|--|---------------------------------|----------|
| | 2010 | 2009 |
| Net income | \$17,492 | \$2,879 |
| Other comprehensive income (loss): | | |
| Unrealized loss on cross-currency swap, net of tax | (445) | (1,889) |
| Foreign currency translation adjustment | (2,897) | (926) |
| Total comprehensive income | \$14,150 | \$64 |

NOTE 12: 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:

9

Table of Contents

Domestic

Domestic (“Domestic”) consists of the operations of Orthofix Inc. within the U.S. Domestic 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 U.S. 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 HCT/P 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 U.S. International uses both direct and distributor sales representatives to sell Spine, Orthopedics, Sports Medicine 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 U.S. holding company subsidiary, Orthofix Holdings, Inc.

The following tables below present information by reportable segment for the three months ended March 31:

| (US\$ in thousands) | External Sales | | Intersegment Sales | |
|-------------------------------|----------------|------------|--------------------|----------|
| | 2010 | 2009 | 2010 | 2009 |
| Domestic | \$ 55,386 | \$ 49,797 | \$ 1,603 | \$ 1,580 |
| Spinal Implants and Biologics | 29,326 | 28,519 | 478 | 365 |
| Breg | 22,509 | 23,110 | 1,285 | 1,510 |
| International | 31,602 | 27,548 | 4,936 | 4,638 |
| Total | \$ 138,823 | \$ 128,974 | \$ 8,302 | \$ 8,093 |

The following table presents operating income (loss) by segment for the three months ended March 31:

| Operating Income (Loss) (US\$ in thousands) | Three Months Ended March 31, | |
|--|---------------------------------|-------------|
| | 2010 | 2009 |
| Domestic | \$ 16,489 | \$ 16,652 |
| Spinal Implants and Biologics | 540 (1) | (7,732)(2) |
| Breg | 1,019 (3) | 3,030 |
| International | 17,156 (4) | 3,674 |
| Group Activities | (4,103) | (5,472) |
| Eliminations | 844 | 348 |
| Total | \$ 31,945 | \$ 10,500 |

(1) Includes \$1.9 million of inventory obsolescence charges related to the discontinuation of the U.S. Advent™ Cervical disc clinical trial.

10

Table of Contents

- (2) Includes \$2.8 million of research and development expense from collaborative arrangements and \$1.3 million of restructuring charges.
- (3) Includes \$1.7 million of insurance expense to cover new product liability claims from its former pain management operations sold in 2008.
- (4) Includes \$12.5 million gain on the sale of vascular operations (see Note 18).

The following tables present sales by market sector for the three months ended March 31, 2010 and 2009:

Sales by Market Sector for the three month period ended March 31,
2010

| (US\$ in thousands) | Domestic | Spinal Implants and Biologics | Breg | International | Total |
|---------------------|----------|--|----------|---------------|-----------|
| Spine | \$41,910 | \$29,326 | \$- | \$ 447 | \$71,683 |
| Orthopedics | 13,476 | - | - | 22,773 | 36,249 |
| Sports Medicine | - | - | 22,509 | 1,092 | 23,601 |
| Vascular | - | - | - | 3,069 | 3,069 |
| Other | - | - | - | 4,221 | 4,221 |
| Total | \$55,386 | \$29,326 | \$22,509 | \$ 31,602 | \$138,823 |

Sales by Market Sector for the three month period ended March 31,
2009

| (US\$ in thousands) | Domestic | Spinal Implants and Biologics | Breg | International | Total |
|---------------------|----------|--|----------|---------------|-----------|
| Spine | \$37,283 | \$28,519 | \$- | \$ 326 | \$66,128 |
| Orthopedics | 12,514 | - | - | 17,079 | 29,593 |
| Sports Medicine | - | - | 23,110 | 1,136 | 24,246 |
| Vascular | - | - | - | 4,408 | 4,408 |
| Other | - | - | - | 4,599 | 4,599 |
| Total | \$49,797 | \$28,519 | \$23,110 | \$ 27,548 | \$128,974 |

NOTE 13:

RESTRUCTURING CHARGES

In the fourth quarter of 2008, as part of the Company's strategic plan to strengthen the business, 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 operations previously conducted in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and U.S. orthopedics business in the Dallas, TX area. The Company plans to complete the restructuring and consolidation by the second quarter of 2010, at which time the Company anticipates a total restructuring expense of \$3.6 million. During the three months ended March 31, 2010, the Company did not record any restructuring charges.

Table of Contents

The following table presents changes in the restructuring liability for the activity discussed above, which is included within Other Current Liabilities in the Company's consolidated balance sheets as of March 31, 2010 and December 31, 2009:

| (US\$ in thousands) | Severance | Assets Abandoned | Total |
|------------------------------|-----------|---------------------|----------|
| Balance at December 31, 2009 | \$ 1,826 | \$ - | \$ 1,826 |
| Charges | - | - | - |
| Cash Payments | (422) | - | (422) |
| Non-cash Items | - | - | - |
| Balance at March 31, 2010 | \$ 1,404 | \$ - | \$ 1,404 |

NOTE 14:

INCOME TAXES

The reported year to date tax provision as a percentage of income before income taxes was 33.0%. The principal factors affecting the Company's tax rate are the gain on the sale of the vascular operations and the Company's mix of earnings among various tax jurisdictions. The reported tax rate was also affected by current period losses in certain foreign jurisdictions for which the Company does not currently provide a tax benefit. Without the sale of the vascular operations the Company's tax rate would have been approximately 38.3%.

As of March 31, 2010, the Company's gross unrecognized tax benefit was \$0.8 million. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within its global operations in income tax expense. As of March 31, 2010, the Company had approximately \$0.4 million accrued for interest and penalties. The entire \$0.8 million of unrecognized tax benefit would affect the Company's effective tax rate if recognized. The Company does not anticipate that the amount of unrecognized tax benefits will change materially over the next twelve months.

The Company is subject to tax examinations in all major taxing jurisdictions in which it operates. The Company files a consolidated income tax return in the U.S. federal jurisdiction and numerous consolidated and separate income tax returns in many state and foreign jurisdictions. The statute of limitations with respect to U.S. federal tax filings is closed for years prior to December 31, 2006. The statute of limitations for the various U.S. state tax filings is closed in most instances for years prior to December 31, 2006. There are certain U.S. 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, 2005.

NOTE 15:

EARNINGS PER SHARE

For the three months ended March 31, 2010, 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 March 31, | |
|--|---------------------------------|------------|
| | 2010 | 2009 |
| Weighted average common shares-basic | 17,489,315 | 17,103,543 |
| Effect of dilutive securities | 267,784 | 18,028 |
| Weighted average common shares-diluted | 17,757,099 | 17,121,571 |

Table of Contents

For the three months ended March 31, 2010 and 2009, the Company did not include 1,771,304 and 3,011,105 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 16:

DERIVATIVE INSTRUMENTS

In 2006, the Company entered into a cross-currency swap agreement to manage its cash flows related to foreign currency exposure for a portion of the Company's intercompany receivable of a U.S. dollar functional currency subsidiary that is denominated in Euro. The derivative instrument, a ten-year fully amortizable agreement with an initial notional amount of \$63.0 million, 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 March 31, 2010 and December 31, 2009 is \$53.5 million. Under the agreement, the Company pays Euro and receives U.S. 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 \$(0.4) million and \$(1.9) million, net of tax, within other comprehensive income in the three months ended March 31, 2010 and 2009, respectively.

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. The amount outstanding under the Swap as of March 31, 2010 was \$150.0 million. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's amended credit facility, the Swap was no longer deemed highly effective. Special hedge accounting is no longer applied and fair value adjustments are reported in current earnings through the expiration of the Swap in June 2011. For the three months ended March 31, 2010 and 2009 the Company recorded an unrealized gain of \$0.3 million and \$0.2 million, respectively, in the statement of operations. 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 ASC Topic 815 – Derivatives and Hedging, the tables below disclose the types of derivative instruments the Company owns, the classifications and fair values of these instruments within the balance sheet, and the amount of gain (loss) recognized in other comprehensive income (loss) ("OCI") or net income (loss).

(US\$ in thousands)

| | Fair value: favorable (unfavorable) | Balance sheet location | Amount of gain (loss) recognized in OCI |
|----------------------|---|-----------------------------|--|
| As of March 31, 2010 | | | |
| Cross-currency swap | \$ (1,492) | Other long-term liabilities | \$(445) |
| Interest rate swap | \$ (5,778) | Other current liabilities | \$- |
| As of March 31, 2009 | | | |
| Cross-currency swap | \$1,328 | Other long-term assets | \$(1,889) |
| Interest rate swap | \$(7,737) | Other current liabilities | \$- |

| | For the three months ended March 31, | |
|--|---|--------|
| (US\$ in thousands) | 2010 | 2009 |
| Amount of gain (loss) recognized in net income | | |
| Interest rate swap | \$ 345 | \$ 239 |

Table of Contents

NOTE 17:

FAIR VALUE MEASUREMENTS

The Company adopted the accounting guidance for fair value measurements on January 1, 2008. Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Non-financial assets and liabilities of the Company measured at fair value include any long-lived assets or equity method investments that are impaired in a currently reported period. The authoritative guidance also describes three levels of inputs that may be used to measure fair value:

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

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

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

As of March 31, 2010, the Company held certain items that are required to be measured at fair value on a recurring basis. These included cash equivalents, restricted cash, accounts receivable, short-term bank borrowings, accounts payable, long-term secured debt, 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 original maturities of 90 days or less, including money market funds. Restricted cash, accounts receivable, short-term bank borrowings and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company's long-term secured debt carries a floating rate of interest and therefore, the carrying value is considered to approximate the fair value. The derivative instruments are related to the Company's interest rate and foreign currency hedges.

The Company's interest rate derivative instrument also consists of an over-the-counter ("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 Company's cross currency derivative instrument consists of an OTC contract, which is not traded on a public exchange. The fair value of the swap contract is determined based on inputs that are readily available in public markets or can be derived from information available in publicly quoted markets. Therefore, the Company has categorized the swap contract as a Level 2 derivative financial instrument. The Company also considers counterparty credit risk and its own credit risk in its determination of all estimated fair values. The Company has consistently applied these valuation techniques in all periods presented.

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

| (US\$ in thousands) | Balance March 31, 2010 | Level 1 | Level 2 | Level 3 |
|-------------------------------------|------------------------------|---------|------------|---------|
| Derivative Financial Instruments(1) | | | | |
| Cash Flow Hedges | | | | |
| Interest rate hedge | \$(5,778) | \$- | \$(5,778) | \$- |
| Cross currency hedge | \$(1,492) | \$- | \$(1,492) | \$- |

(1)

See Note 16, "Derivative Instruments".

NOTE 18:

SALE OF VASCULAR OPERATIONS

On March 8, 2010, the Company and certain of its subsidiaries (the “Orthofix Parties”) entered into an asset purchase agreement (the “APA”) with Tyco Healthcare Group LP d/b/a Covidien, Covidien AG, and certain of their affiliates (collectively, the “Covidien Parties”). Prior to the parties entering into the APA, certain of the Covidien Parties had been serving as distributors with respect to the Orthofix Parties’ A-V IMPULSE SYSTEM® products.

14

Table of Contents

Pursuant to the terms of the APA, the Orthofix Parties agreed to sell to the Covidien Parties substantially all of the Orthofix Parties' collective assets related to the A-V IMPULSE SYSTEM® and related accessories (including finished goods inventory and tangible assets). At the closing, the Covidien Parties paid a cash purchase price of approximately \$27.7 million, which amount includes the estimated value of certain finished goods inventory conveyed at the closing, and remains subject to post-closing verification.

Pursuant to the APA, the Orthofix Parties agreed to enter into certain transition arrangements at the closing under the APA, including (i) a transition services agreement with the Covidien Parties pursuant to which, among other things, the Orthofix Parties will continue to provide operational support with respect to the transferred assets in certain jurisdictions for a period of up to five months, and (ii) two separate supply agreements with certain of the Covidien Parties pursuant to which, among other things, certain of the Orthofix Parties will provide manufacturing and logistics services on behalf of Covidien with respect to certain ImPads for a period of two years and provide other products for a period of 90 days. The Orthofix Parties also agreed to enter into a 5-year noncompetition agreement at closing with respect to the business of the assets being transferred.

The following table presents the value of the asset disposition, including the cash purchase price, cash proceeds received, net of litigation costs and gain on the sale of the vascular operations as shown in the Condensed Consolidated Statements of Operations for the three months ended March 31, 2010.

| (US\$ in thousands) | Total |
|---|-----------|
| Gross cash proceeds received from sale of vascular operations | \$ 27,701 |
| Litigation settlement(1) | 3,508 |
| Cash proceeds, net of litigation | 24,193 |
| Less: | |
| Transaction related expenses | 1,699 |
| Inventory | 1,570 |
| Tangible assets | 799 |
| Identifiable intangible assets | 543 |
| Goodwill | 7,031 |
| Pre-tax gain on sale of vascular operations | 12,551 |
| Income tax expense | 3,498 |
| Net gain on sale of vascular operations | \$ 9,053 |

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

NOTE 19:

CONTINGENCIES

Litigation

On or about July 23, 2007, our subsidiary, Blackstone Medical Inc. ("Blackstone") received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks documents for the period January 1, 2000 through July 31, 2006, which is prior to Blackstone's acquisition by 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's indemnification rights under the Blackstone Merger Agreement are described further below). The Company was subsequently notified by legal counsel

for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

Table of Contents

On or about January 7, 2008, the Company received a federal grand jury subpoena from the U.S. Attorney's Office for the District of Massachusetts. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On or about April 29, 2009, counsel for the Company received a HIPAA subpoena issued by the U.S. Department of Justice. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters, as well as the January 7, 2008 federal grand jury subpoena. On or about April 23, 2010, counsel for Orthofix Inc. and Blackstone executed a tolling agreement with the U.S. Attorney's Office for the District of Massachusetts (the "Tolling Agreement") that extends an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate to include the period from December 1, 2008 through and including June 30, 2010.

On or about December 5, 2008, the Company obtained a copy of a qui tam complaint filed by Susan Hutcheson and Philip Brown against Blackstone and the Company in the U.S. District Court for the District of Massachusetts. A qui tam action is a civil lawsuit brought by an individual for an alleged violation of a federal statute, in which the U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. On November 21, 2008, the U.S. Department of Justice filed a notice of non-intervention in the case. The complaint was served on Blackstone on or about March 24, 2009. Counsel for the plaintiffs filed an amended complaint on June 4, 2009. The amended complaint sets forth a cause of action against Blackstone under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants; Orthofix is not named as a defendant in the amended complaint. The Company believes that this lawsuit is related to the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and the U.S. Attorney's Office for the District of Massachusetts, and the U.S. Department of Justice. The Company intends to defend vigorously against this lawsuit. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of the U.S. Department of Justice and prior to the unsealing of the complaint (which was unsealed by the court on or about November 24, 2008), the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. On or about March 12, 2010, the United States District Court for the District of Massachusetts granted Blackstone's motion to dismiss and, on March 15, 2010, entered judgment in favor of Blackstone. On or about April 9, 2010, the qui tam relators filed a notice of appeal of the district court decision to the United States Court of Appeals for the First Circuit.

On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the U.S. Attorney's Office for the District of Nevada ("USAO-Nevada subpoena"). The subpoena seeks documents for the period from January 1999 to the date of issuance of the subpoena. The Company believes that the subpoena concerns payments or gifts made by Blackstone to certain physicians. On February 29, 2008, Blackstone received a Civil Investigative Demand ("CID") from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. The CID seeks documents for the period from March 2004 through the date of issuance of the CID, and the Company believes that the CID concerns Blackstone's financial relationships with certain physicians and related matters. The Ohio Attorney General's Office, Health Care Fraud Section has issued a criminal subpoena, dated August 8, 2008, to Orthofix, Inc. (the "Ohio AG subpoena"). The Ohio AG subpoena seeks documents for the period from January 1, 2000 through the date of issuance of the subpoena. The Company believes that the Ohio AG subpoena arises from a government investigation that concerns the compensation of physician consultants and related matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from the USAO-Nevada subpoena,

the Massachusetts CID and the Ohio AG subpoena.

By order entered on January 4, 2007, the U.S. District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. The amended complaint in the Thomas action alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan and another provider. 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.

Table of Contents

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have agreed to indemnify the Company for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders are limited to a cumulative aggregate amount of \$66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was \$50.0 million. As of March 31, 2010, the escrow fund, which has subsequently accrued interest, contained \$52 million. The Company is also entitled to seek direct personal recourse against certain principal shareholders of Blackstone after all monies on deposit in the escrow fund have been paid out or released or are the subject of pending or unresolved indemnification claims but only for a period of six years from the closing date of the merger and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

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

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 the Company from these matters will not exceed the amount of the escrow fund. Expenses incurred by the Company relating to the above matters are recorded as an escrow receivable in the Company's financial statements to the extent the Company believes, among other things, that collection of the claims is reasonably assured. Expenditures related to such matters for which the Company believes collection is doubtful are recognized in earnings when incurred. As of March 31, 2010 and December 31, 2009, included in Prepaid expenses and other current assets is approximately \$13.4 million and \$12.9 million, respectively, of escrow receivable balances related to the Blackstone matters described above. These amounts include, among other things, attorneys' fees and costs related to the government investigations manifested by the subpoenas described above, the stock option-related claims described above, and costs related to the qui tam actions described above. As described above, some of these reimbursement claims are being contested by the representative of the former shareholders of Blackstone. To mitigate the risk that some reimbursement claims will not be collected, the Company records a reserve against the escrow receivable during the period in which reimbursement claims are recognized.

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

Table of Contents

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 “Boston USAO”). The subpoena sought documents concerning, among other things, the Company’s promotion and marketing of its bone growth stimulator devices. The Boston USAO issued a supplemental subpoena in this matter dated July 23, 2009, requiring testimony. That office later excused performance with the July 23, 2009 subpoena indefinitely. The Boston USAO also issued supplemental subpoenas in this matter, dated September 21, 2009 and December 16, 2009, respectively, seeking documents. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. Document production in response to the subpoenas is ongoing. On December 21, 2009, the Boston USAO provided the Company with grand jury subpoenas for the testimony of certain current employees in connection with its ongoing investigation. The Company intends to cooperate with the government’s requests. In meetings with the Company and its attorneys regarding this matter, the Boston USAO has informed the Company that it is investigating possible criminal and civil violations of federal law related to the Company’s promotion and marketing of its bone growth stimulator devices.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the U.S. District Court for the District of Massachusetts against 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. The Company and Orthofix, Inc. were served on or about September 8, 2009. 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 U.S. 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 complaint alleges violations of the False Claims Act, fraudulent billing, illegal kickbacks and wrongful termination based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products, 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 complaint also alleges that TRICARE has been reimbursing the Company for its Cervical Stim® product without approval to do so. An amended complaint alleges conspiracy and violations of the Sherman Anti-Trust Act in connection with the same alleged conduct. The Company was served with the complaint on or about September 9, 2009. The Company intends to defend vigorously against this lawsuit.

Our subsidiary, Breg, Inc., was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008, when the product line was divested. As between 2008 and present, numerous product liability cases have been filed in the United States alleging that the local anesthetic, when dispensed by such infusion pumps inside a joint, causes a rare arthritic condition called “chondrolysis.” The Company believes that meritorious defenses exist to these claims and Breg, Inc. intends to vigorously defend these cases.

On April 22, 2010, the Company obtained a copy of a complaint filed by NuVasive, Inc. (“NuVasive”) and Osiris Therapeutics, Inc. (“Osiris”) in the U.S. District Court for the District of New Jersey against Orthofix International N.V., Orthofix, Inc., Orthofix Holdings, Inc., Orthofix Biologics, Orthofix Spinal Implants, and Musculoskeletal Transplant Foundation. The complaint alleges that the Company’s Trinity® Evolution™ allograft product infringes a U.S. patent

owned by Osiris and licensed to NuVasive. The complaint requests the court to enjoin the sale of Trinity® Evolution™ and award damages to NuVasive and Osiris for the alleged infringement. The Company believes that it has meritorious defenses to the claims alleged and the Company intends to defend vigorously against this lawsuit.

Table of Contents

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. To the extent losses related to these contingencies are both probable and estimable, the Company provides appropriate amounts in the accompanying financial statements.

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

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 months ended March 31, 2010 compared to our results of operations for the three months ended March 31, 2009. 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, 2009.

General Overview

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 believe the keys to reaching our publicly stated financial goals for 2010 include:

- An increase in revenue driven by the introduction of a number of key new products that were launched in 2009, including the Trinity® Evolution™ allograft, the Firebird™ pedicle screw system, the PILLAR™ SA interbody device, and the Ascent® LE posterior cervical spine system.
- An increase in gross profit margin driven by a full year of sales of our key new products indicated above, primarily Trinity® Evolution™. While we record 70% of the sales price of Trinity® Evolution™ allograft versus recording 100% of the sales price of the old Trinity® product, we recognize a 100% gross profit margin from the marketing fees earned from the sales of this allograft, compared to approximately 50% gross profit margin on our previous Trinity® product. This is due to the fact that we are not required to purchase inventory of Trinity® Evolution™, whereas, previously, we were required to purchase inventory of the old Trinity® product and record the associated cost of sales.
- A decrease in operating expenses as a percentage of revenue as we continue to leverage our operating infrastructure against the increase in revenues noted above. In 2008, we initiated a reorganization and consolidation plan to reduce operating expenses by eliminating the redundancies and increasing operating efficiency. This plan included the consolidation of our Springfield, MA and Wayne, NJ locations into our operations in the Dallas, TX area. For a further discussion about this reorganization and consolidation plan, please refer to the explanation provided in our Liquidity and Capital Resources section of the Management Discussion and Analysis.
 - A continuation of strong financial performance from all of our segments.

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 expense, net on the statements of operations. Gains and losses resulting from the translation of foreign currency net assets are recorded in the accumulated other comprehensive income component of shareholders' equity.

Table of Contents

Our financial condition, results of operations and cash flows are not significantly impacted by seasonality trends. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. Certain of the Breg® bracing products experience greater demand in the fall and winter corresponding with high school and college football schedules and winter sports. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar denominated income and expenditures. During the three months ended March 31, 2010, we have used derivative instruments to hedge foreign currency fluctuation exposures. 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 U.S. holding company subsidiary, Orthofix Holdings, Inc.

Segment and Market Sector Revenues

The following tables display net sales by business segment and net sales by market sector. We maintain our 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 March 31, | | 2009 | | Growth |
|-------------------------------|------------------------------|----------------------------|-----------|----------------------------|--------|
| | 2010 | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales | |
| Domestic | \$55,386 | 40 % | \$49,797 | 39 % | 11 % |
| Spinal Implants and Biologics | 29,326 | 21 % | 28,519 | 22 % | 3 % |
| Breg | 22,509 | 16 % | 23,110 | 18 % | -3 % |
| International | 31,602 | 23 % | 27,548 | 21 % | 15 % |
| Total | \$138,823 | 100 % | \$128,974 | 100 % | 8 % |

Table of Contents

Market Sector:

| (US\$ in thousands) | Three Months Ended March 31, | | | | | | Reported Growth | Constant Currency Growth |
|---------------------|------------------------------|----------------------------|---|-----------|----------------------------|---|-----------------|--------------------------|
| | 2010 | Percent of Total Net Sales | | 2009 | Percent of Total Net Sales | | | |
| | Net Sales | | | Net Sales | | | | |
| Spine | \$71,683 | 52 | % | \$66,128 | 51 | % | 8 | % |
| Orthopedics | 36,249 | 26 | % | 29,593 | 23 | % | 22 | % |
| Sports Medicine | 23,601 | 17 | % | 24,246 | 19 | % | -3 | % |
| Vascular | 3,069 | 2 | % | 4,408 | 3 | % | -30 | % |
| Other | 4,221 | 3 | % | 4,599 | 4 | % | -8 | % |
| Total | \$138,823 | 100 | % | \$128,974 | 100 | % | 8 | % |

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 March 31, | |
|-------------------------------------|------------------------------|----------|
| | 2010 (%) | 2009 (%) |
| Net sales | 100 | 100 |
| Cost of sales | 24 | 25 |
| Gross profit | 76 | 75 |
| Operating expenses: | | |
| Sales and marketing | 41 | 41 |
| General and administrative | 15 | 18 |
| Research and development | 5 | 7 |
| Amortization of intangible assets | 1 | 1 |
| Gain on sale of vascular operations | (9) | - |
| Total operating income | 23 | 8 |
| Net income | 13 | 2 |

Three Months Ended March 31, 2010 Compared to Three Months Ended March 31, 2009

Net sales increased 8% to \$138.8 million in the first quarter of 2010 compared to \$129.0 million for the same period last year. The impact of foreign currency increased sales by \$2.6 million during the first quarter of 2010 when compared to the first quarter of 2009.

Sales by Business Segment:

Net sales in Domestic increased to \$55.4 million in the first quarter of 2010 compared to \$49.8 million for the same period last year, an increase of 11%. Domestic's net sales represented 40% and 39% of total net sales during the first quarter of 2010 and 2009, respectively. The increase in Domestic's net sales was partially the result of a 12% increase in sales in our Spine market sector, which was mainly driven by increased sales of our Spinal-Stim® and

Cervical-Stim® products, both which increased 12% and 13%, respectively when compared to the same period in the prior year. The increase in Domestic's net sales was also attributable to an 8% increase in our Orthopedics market sector which included a 16% increase in sales of our external fixation products and a 27% increase in our HCT/P products, specifically Trinity® Evolution™.

Table of Contents

Domestic Sales by Market Sector:

| (US\$ in thousands) | Net Sales for the | | Growth | |
|---------------------|------------------------------|-----------|--------|---|
| | Three Months Ended March 31, | | | |
| | 2010 | 2009 | | |
| Spine | \$ 41,910 | \$ 37,283 | 12 | % |
| Orthopedics | 13,476 | 12,514 | 8 | % |
| Total | \$ 55,386 | \$ 49,797 | 11 | % |

Net sales in Spinal Implants and Biologics increased \$0.8 million to \$29.3 million in the first quarter of 2010 compared to \$28.5 million for the same period last year, an increase of 3%. Spinal Implants and Biologics' net sales represented 21% and 22% of total net sales during the first quarter of 2010 and 2009, respectively. The increase in sales was primarily related to a 13% increase in our thoracolumbar products due to the introduction of the Firebird™ pedicle screw system which was introduced during the second quarter of 2009. Sales of our interbody products increased by 27%, when compared to the same period in the prior year, as a result of the introduction of the Pillar™ SA interbody device which was introduced during the third quarter of 2009. These sales increases were partially offset by a 26% sales decrease in our biologics products when compared to the same period last year as a result of our replacement of the Trinity® product line with Trinity® Evolution™. Although biologics sales decreased, the quantity of product sold increased in the first quarter of 2010 compared to the first quarter of 2009. Full market release of our Trinity® Evolution™ stem cell-based allograft occurred on July 1, 2009. All of Spinal Implants and Biologics' sales are recorded in our Spine market sector.

Net sales in Breg decreased \$0.6 million to \$22.5 million in the first quarter of 2010 compared to \$23.1 million for the same period last year, a decrease of 3%. Breg's net sales represented 16% and 18% of total net sales during the first quarter of 2010 and 2009, respectively. The decrease in net sales includes the impact of a revenue reclassification where commissions for a certain distributor are now netted against the gross revenue. Excluding the impact of this change, net sales in Breg for the first quarter of 2010 would have decreased by 1% when compared with the same period in the prior year. The decrease in Breg's net sales was primarily due to a 4% reduction in sales of our Breg bracing products when compared to the same period in the prior year. We continue to see a trend where the number of elective surgeries is declining. Sales of our cold therapy products increased 4% over the same period in the prior year which helped to partially offset the overall net sales decrease. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International increased 15% to \$31.6 million in the first quarter of 2010 compared to \$27.5 million for the same period last year. International's net sales represented 23% and 21% of our total net sales in the first quarter of 2010 and 2009, respectively. The impact of foreign currency increased International net sales by 9% or \$2.5 million, during the first quarter of 2010 as compared to the first quarter of 2009. On a constant currency basis, sales for the Orthopedics sector increased 22% in the first quarter of 2010 when compared to the prior year. Within the Orthopedics sector, external fixation, internal fixation and deformity correction increased 23%, 30% and 44% 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®, decreased 32% on a constant currency basis when compared to the first quarter of 2009. This decrease is mainly the result of the asset disposition of our vascular operations in March 2010. See further discussion in the Gain on Sale of Vascular Operations below. Our Other distributed products, primarily the Laryngeal Mask, decreased 17% on a constant currency basis when compared to the first quarter of 2009. In October 2009, we transitioned out of our agreement to distribute the Laryngeal Mask product in Italy. We will transition out of our agreement to distribute the Laryngeal Mask product in the United Kingdom in June 2010.

Table of Contents

International Sales by Market Sector:

| (US\$ in thousands) | Net Sales for the Three Months Ended March 31, | | | | Constant Currency Growth | |
|---------------------|---|-----------|--------------------|---|--------------------------------|---|
| | 2010 | 2009 | Reported Growth | | | |
| Spine | \$ 447 | \$ 326 | 37 | % | 36 | % |
| Orthopedics | 22,773 | 17,079 | 33 | % | 22 | % |
| Sports Medicine | 1,092 | 1,136 | -4 | % | -10 | % |
| Vascular | 3,069 | 4,408 | -30 | % | -32 | % |
| Other | 4,221 | 4,599 | -8 | % | -17 | % |
| Total | \$ 31,602 | \$ 27,548 | 15 | % | 5 | % |

Sales by Market Sector:

Sales of our Spine products increased to \$71.7 million in the first quarter of 2010 compared to \$66.1 million in the first quarter of 2009. Sales of our Cervical-Stim® and Spinal-Stim® products increased 13% and 12%, respectively, in the first quarter of 2010 compared to 2009. In addition, sales of our Spinal Implants and Biologics products increased 3% over the same period in the prior year due to the introduction of new thoracolumbar products previously discussed as well as increased sales of our interbody and cervical products. Spine product sales were 52% and 51% of our total net sales in the first quarter of 2010 and 2009, respectively.

Sales of our Orthopedics products increased \$6.6 million to \$36.2 million in the first quarter of 2010 compared to \$29.6 million for the same period last year. Sales increased 22% compared to the same period last year due to increased sales of our internal fixation, external fixation, deformity correction and HCT/P products. Orthopedic product sales were 26% and 23% of our total net sales in the first quarter of 2010 and 2009, respectively.

Sales of our Sports Medicine products decreased 3% to \$23.6 million in the first quarter of 2010 compared to \$24.2 million for the same period last year. As discussed above, net sales would have decreased by 1% when comparing the first quarter of 2010 to the same period in the prior year, had it not been for a reclassification of certain commissions which are reflected as a reduction of gross revenue, but were originally recorded in operating expenses. Sports Medicine product sales were 17% and 19% of our total net sales in the first quarter of 2010 and 2009, respectively.

Sales of our Vascular products, which consist of our A-V IMPULSE SYSTEM®, decreased 30% to \$3.1 million in the first quarter of 2010 compared to \$4.4 million for the same period last year. This decrease is mainly the result of the asset disposition of our vascular operations in March 2010. See further discussion in the Gain on Sale of Vascular Operations below. Vascular product sales were 2% and 3% of our total net sales in the first quarter of 2010 and 2009, respectively.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our Woman's Care line, decreased 8% to \$4.2 million in the first quarter of 2010 when compared to \$4.6 million for the same period last year. On a constant currency basis, sales decreased 17% when compared to the first quarter of 2009. In October 2009, we transitioned out of our agreement to distribute the Laryngeal Mask product in Italy. We will transition out of our agreement to distribute the Laryngeal Mask product in the United Kingdom in June 2010. Other product sales were 3% and 4% of our total net sales in the first quarter of 2010 and 2009, respectively.

Table of Contents

Gross Profit – Our gross profit increased 10% to \$106.1 million in the first quarter of 2010, compared to \$96.2 million for the same period last year. Gross profit as a percent of net sales in the first quarter of 2010 was 76.4% compared to 74.6% for the same period last year. The gross profit in the first quarter of 2010 also includes the impact of a \$1.9 million increase in the provision for inventory obsolescence recorded in connection with the discontinued U.S. Advent™ Cervical disc clinical trial. Excluding the impact of this adjustment, gross profit as a percent of net sales in the first quarter of 2010 would have been 77.8%. The increase in the gross profit is primarily due to the increased sales of higher margin stimulation products and Spinal Implants and Biologics products. As mentioned previously, while we record 70% of the sales price of Trinity® Evolution™ allograft versus recording 100% of the sales price of the old Trinity® product, we recognize a 100% gross profit margin from the marketing fees earned from the sales of this allograft, compared to approximately 50% gross profit margin on our previous Trinity® product. This is due to the fact that we are not required to purchase inventory of Trinity® Evolution™, whereas, previously, we were required to purchase inventory of the old Trinity® product and record the associated cost of sales.

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 \$4.0 million, or 8%, to \$56.3 million in the first quarter of 2010 compared to \$52.3 million in the first quarter of 2009. As a percent of net sales, sales and marketing expense was 40.5% in the first quarter of both 2010 and 2009.

General and Administrative Expense – General and administrative expense decreased \$1.2 million, or 5%, in the first quarter of 2010 to \$21.5 million compared to \$22.7 million in the first quarter of 2009. The decrease is primarily due to a restructuring charge of \$1.3 million that was recorded during the first quarter of 2009 resulting from the initiation of a reorganization and consolidation plan to reduce operating expenses by eliminating redundancies and increasing operating efficiency. In addition, during the first quarter of 2009, the Company incurred \$0.7 million of costs incurred in connection with a proxy contest. General and administrative expense as a percent of net sales was 15.5% in the first quarter of 2010 compared to 17.6% for the same period last year.

Research and Development Expense – Research and development expense decreased \$1.6 million in the first quarter of 2010 to \$7.5 million compared to \$9.1 million for the same period last year. During the first quarter of 2009, we incurred approximately \$1.8 million in expenses from our collaborative arrangement with the Musculoskeletal Transplant Foundation (“MTF”). As a percent of sales, research and development expense was 5.4% in the first quarter of 2010 compared to 7.0% for the same period last year.

Amortization of Intangible Assets – Amortization of intangible assets decreased \$0.2 million in the first quarter of 2010 to \$1.4 million compared to \$1.6 million for the same period last year.

Gain on Sale of Vascular Operations – Gain on sale of Vascular Operations was \$12.6 million in the first quarter of 2010 and represented the gain on the sale of our vascular operations related to the A-V IMPULSE SYSTEM® and related accessories on March 8, 2010. No such gain was recorded in the first quarter of 2009.

Interest Expense, net – Interest expense, net was \$5.8 million for the first quarter of 2010 compared to \$6.1 million for the same period last year, primarily the result of a lower year over year outstanding debt balance, partially offset by a higher rate of effective interest.

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 determined that the Swap was no longer deemed highly effective. Therefore, special hedge 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. The Company recorded an unrealized non-cash gain of \$0.3 million and \$0.2 million during the first quarter of 2010 and 2009, respectively.

Table of Contents

Other Expense, net – Other expense, net reflected an expense of \$0.3 million for both the first quarter of 2010 and 2009. These charges are mainly related for foreign exchange. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies.

Income Tax Expense – Our effective tax rate as a percentage of income was 33.0% during the first quarters of 2010 and 2009. The effective tax rate for the first quarter of 2010 was affected by the gain on the sale of vascular operations and the mix of earnings among various tax jurisdictions. Without the sale of the vascular operations the Company's tax rate would have been approximately 38.3%. The Company incurs losses in a number of foreign jurisdictions for which the Company does not currently take a tax benefit. The Company does not believe that it is more likely than not that it will generate sufficient future income in these jurisdictions to allow for the utilization of these losses before their expiration.

Net Income – Net income for the first quarter of 2010 was \$17.5 million, or \$1.00 per basic and \$0.99 per diluted share, compared to a net income of \$2.9 million, or \$0.17 per basic and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,489,315 and 17,103,543 during the first quarters of 2010 and 2009, respectively. The weighted average number of diluted common shares outstanding was 17,757,099 and 17,121,571 during the first quarters of 2010 and 2009, respectively.

Liquidity and Capital Resources

Cash and cash equivalents at March 31, 2010 were \$34.7 million, of which \$16.0 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$25.0 million at December 31, 2009, of which \$11.6 million was restricted.

Net cash used in operating activities was (\$0.4) million for the three months ended March 31, 2010 compared to net cash provided by operating activities of \$11.1 million for the same period last year. Net cash used in 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, deferred taxes, and gain on sale of vascular operations) and changes in working capital, including changes in restricted cash. Net income increased \$14.6 million to \$17.5 million for the three months ended March 31, 2010 from net income of \$2.9 million for the comparable period in the prior year. Non-cash expense for the three months ended March 31, 2010 decreased \$13.4 million compared to the same period last year primarily as a result of the gain on the sale of vascular operations of \$12.6 million and a decrease in deferred taxes of \$1.3 million. These decreases were partially offset by an increase in the inventory provision of \$1.1 million. Working capital accounts consumed \$17.1 million of cash in the three months ended March 31, 2010 compared to \$4.4 million for the same period last year. The principal change in working capital can be mainly attributed to an increase in the trade accounts receivable position of \$6.7 million, an increase in the restricted cash of \$4.2 million, and a decrease in the trade accounts payable position of \$2.4 million, offset by a decrease in our inventory position of \$4.0 million. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 87 days at March 31, 2010 compared to 76 days at March 31, 2009 and inventory turns of 1.5 times at March 31, 2010 compared to 1.4 times at March 31, 2009. The increase in days sales in receivables was due to a higher portion of sales in the first quarter of 2010 occurring in the last month of the quarter.

Net cash provided by investing activities was \$19.8 million during the three months ended March 31, 2010 compared to net cash used in investing activities of (\$3.5) million during the same period last year. During the first quarter of 2010, we sold our vascular operations with cash proceeds, net of litigation, of \$24.2 million. During the three months ended March 31, 2010 and 2009, we invested \$4.4 million and \$3.5 million in capital expenditures, respectively.

Net cash used in financing activities was \$13.6 million for the three months ended March 31, 2010 compared to \$15.1 million for the same period last year. During the three months ended March 31, 2010, we repaid approximately \$19.8 million against the principal on our senior secured term loan compared to \$12.8 million during the three months ended March 31, 2009. During the three months ended March 31, 2010, we received proceeds of \$4.6 million from the issuance of 405,327 shares of our common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

Table of Contents

On September 22, 2006 the Company's wholly-owned U.S. 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 on September 29, 2008 and February 24, 2010. 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 March 31, 2010, the Company had \$0.3 million of letters of credit outstanding under the revolving credit facility and \$232.6 million outstanding under the term loan facility. Obligations under the senior secured credit facility can 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. As of March 31, 2010, the entire term loan obligation of \$232.6 million is at the prime rate plus a margin of 3.50%.

The Company made a mandatory payment on its principal balance amounting to \$19.0 million on March 31, 2010. This principal payment represented all of the preliminary net proceeds the Company received on the sale of its vascular operations on March 8, 2010.

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. The Company was in compliance with these financial covenants as measured at March 31, 2010. As defined in the senior secured credit facility, our leverage ratio can not exceed 2.85 and our fixed charge ratio must be greater than or equal to 1.375. At March 31, 2010, our leverage and fixed charge ratios were 2.11 and 1.74, respectively.

The leverage ratio the Company cannot exceed, as defined in the senior secured credit facility, is 2.85 for the first quarter of 2010, 2.75 for the second quarter of 2010 and 2.50 thereafter. The fixed charge coverage ratio must be greater than 1.375 and remain at that rate for the remaining life of the senior secured credit facility. Based on the Company's projected earnings, we believe that the Company 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.

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 March 31, 2010 is \$170.9 million compared to \$143.0 million at December 31, 2009. 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 March 31, 2010 is \$16.0 million compared to \$11.6 million at December 31, 2009.

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 March 31, 2010 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 March 31, 2010, the effective interest rate on the debt related to the Swap was 10.2%. Our overall effective interest

rate, including the impact of the Swap as of March 31, 2010 on our senior secured debt was 9.0%.

Table of Contents

At March 31, 2010, we had outstanding borrowings of \$2.0 million and unused available lines of credit of approximately 5.8 million Euro (\$7.8 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

We believe that current cash balances together with projected cash flows from operating activities, the availability of the \$44.7 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.

In the fourth quarter of 2008, as part of the Company's strategic plan to strengthen the business, 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 operations previously conducted in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and U.S. orthopedics business in the Dallas, TX area. The Company plans to complete the restructuring and consolidation by the second quarter of 2010, at which time the Company anticipates a total restructuring expense of \$3.6 million. During the three months ended March 31, 2010, the Company did not record any restructuring charges.

The following table presents changes in the restructuring liability for the activity discussed above, which is included within Other Current Liabilities in the Company's consolidated balance sheets as of March 31, 2010 and December 31, 2009:

| (US\$ in thousands) | Severance | Assets Abandoned | Total |
|------------------------------|-----------|---------------------|----------|
| Balance at December 31, 2009 | \$ 1,826 | \$ - | \$ 1,826 |
| Charges | - | - | - |
| Cash Payments | (422) | - | (422) |
| Non-cash Items | - | - | - |
| Balance at March 31, 2010 | \$ 1,404 | \$ - | \$ 1,404 |

On March 8, 2010, the Company and certain of its subsidiaries (the "Orthofix Parties") entered into an asset purchase agreement (the "APA") with Tyco Healthcare Group LP d/b/a Covidien, Covidien AG, and certain of their affiliates (collectively, the "Covidien Parties"). Prior to the parties entering into the APA, certain of the Covidien Parties had been serving as distributors with respect to the Orthofix Parties' A-V IMPULSE SYSTEM® products.

Pursuant to the terms of the APA, the Orthofix Parties agreed to sell to the Covidien Parties substantially all of the Orthofix Parties' collective assets related to the A-V IMPULSE SYSTEM® and related accessories (including finished goods inventory and tangible assets). At the closing, the Covidien Parties paid a cash purchase price of approximately \$27.7 million, which amount includes the estimated value of certain finished goods inventory conveyed at the closing, and remains subject to post-closing verification.

Pursuant to the APA, the Orthofix Parties agreed to enter into certain transition arrangements at the closing under the APA, including (i) a transition services agreement with the Covidien Parties pursuant to which, among other things, the Orthofix Parties will continue to provide operational support with respect to the transferred assets in certain jurisdictions for a period of up to five months, and (ii) two separate supply agreements with certain of the Covidien Parties pursuant to which, among other things, certain of the Orthofix Parties will provide manufacturing and logistics services on behalf of Covidien with respect to certain ImPads for a period of two years and provide other products for a period of 90 days. The Orthofix Parties also agreed to enter into a 5-year noncompetition agreement at closing with

respect to the business of the assets being transferred.

28

Table of Contents

The following table presents the value of the asset disposition, including the cash purchase price, cash proceeds received, net of litigation costs and gain on the sale of the vascular operations for the three months ended March 31, 2010.

| (US\$ in thousands) | Total |
|---|-----------|
| Gross cash proceeds received from sale of vascular operations | \$ 27,701 |
| Litigation settlement(1) | 3,508 |
| Cash proceeds, net of litigation | 24,193 |
| Less: | |
| Transaction related expenses | 1,699 |
| Inventory | 1,570 |
| Tangible assets | 799 |
| Identifiable intangible assets | 543 |
| Goodwill | 7,031 |
| Pre-tax gain on sale of vascular operations | 12,551 |
| Income tax expense | 3,498 |
| Net gain on sale of vascular operations | \$ 9,053 |

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations, and the cost of financing and yields on cash and short-term investments. We use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of March 31, 2010, 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 (if any), 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 March 31, 2010 to minimize interest rate risk related to our LIBOR-based borrowings.

As of March 31, 2010, we had \$232.6 million of variable rate term debt represented by borrowings under our senior secured term loan which can have a floating interest rate of LIBOR plus a margin, with a LIBOR floor of 3.0%, or the prime rate plus a margin. As of March 31, 2010, the entire term loan obligation of \$232.6 million is at the prime rate plus a margin of 3.50%, which is 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 March 31, 2010 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 March 31, 2010, the effective interest rate on the debt related to the Swap was 10.2%. As of March 31, 2010, our overall effective interest rate, including the impact of the Swap, on our senior secured debt was 9.0%. Based on the balance outstanding under the senior secured term loan combined with the Swap as of March 31, 2010, 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 \$2.3 million on an annual basis.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Great Britain Pound, Mexican Peso and Brazilian Real. We are subject to cost of goods currency exposure when we produce products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. As of March 31, 2010, we had an un-hedged intercompany receivable denominated in Euro of approximately 21.6 million (\$29.2 million). We recorded a foreign currency loss during the three months ended March 31, 2010 of \$1.7 million, which resulted from the weakening of the Euro against the U.S. dollar during the period.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the three months ended March 31, 2010 and 2009 by foreign currency exchange rate fluctuations with the weakening of the U.S. dollar against the local foreign currency during this period. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results.

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

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

There have not been any changes in our internal control over financial reporting during the fiscal quarter ended March 31, 2010 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

31

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On or about July 23, 2007, our subsidiary, Blackstone Medical Inc. (“Blackstone”) received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks documents for the period January 1, 2000 through July 31, 2006, which is prior to Blackstone’s acquisition by 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’s indemnification rights under the Blackstone Merger Agreement are described further below). The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

On or about January 7, 2008, the Company received a federal grand jury subpoena from the U.S. Attorney’s Office for the District of Massachusetts. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General’s investigation of such matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On or about April 29, 2009, counsel for the Company received a HIPAA subpoena issued by the U.S. Department of Justice. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General’s investigation of such matters, as well as the January 7, 2008 federal grand jury subpoena. On or about April 23, 2010, counsel for Orthofix Inc. and Blackstone executed a tolling agreement with the U.S. Attorney’s Office for the District of Massachusetts (the “Tolling Agreement”) that extends an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate to include the period from December 1, 2008 through and including June 30, 2010.

On or about December 5, 2008, the Company obtained a copy of a qui tam complaint filed by Susan Hutcheson and Philip Brown against Blackstone and the Company in the U.S. District Court for the District of Massachusetts. A qui tam action is a civil lawsuit brought by an individual for an alleged violation of a federal statute, in which the U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. On November 21, 2008, the U.S. Department of Justice filed a notice of non-intervention in the case. The complaint was served on Blackstone on or about March 24, 2009. Counsel for the plaintiffs filed an amended complaint on June 4, 2009. The amended complaint sets forth a cause of action against Blackstone under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants; Orthofix is not named as a defendant in the amended complaint. The Company believes that this lawsuit is related to the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and the U.S. Attorney’s Office for the District of Massachusetts, and the U.S. Department of Justice. The Company intends to defend vigorously against this lawsuit. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of the U.S. Department of Justice and prior to the unsealing of the complaint (which was unsealed by the court on or about November 24, 2008), the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. On or about March 12, 2010, the United States District Court for the District of Massachusetts granted Blackstone’s

motion to dismiss and, on March 15, 2010, entered judgment in favor of Blackstone. On or about April 9, 2010, the qui tam relators filed a notice of appeal of the district court decision to the United States Court of Appeals for the First Circuit.

Table of Contents

On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the U.S. Attorney's Office for the District of Nevada ("USAO-Nevada subpoena"). The subpoena seeks documents for the period from January 1999 to the date of issuance of the subpoena. The Company believes that the subpoena concerns payments or gifts made by Blackstone to certain physicians. On February 29, 2008, Blackstone received a Civil Investigative Demand ("CID") from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. The CID seeks documents for the period from March 2004 through the date of issuance of the CID, and the Company believes that the CID concerns Blackstone's financial relationships with certain physicians and related matters. The Ohio Attorney General's Office, Health Care Fraud Section has issued a criminal subpoena, dated August 8, 2008, to Orthofix, Inc. (the "Ohio AG subpoena"). The Ohio AG subpoena seeks documents for the period from January 1, 2000 through the date of issuance of the subpoena. The Company believes that the Ohio AG subpoena arises from a government investigation that concerns the compensation of physician consultants and related matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from the USAO-Nevada subpoena, the Massachusetts CID and the Ohio AG subpoena.

By order entered on January 4, 2007, the U.S. District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. The amended complaint in the Thomas action alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan and another provider. 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.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have agreed to indemnify the Company for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders are limited to a cumulative aggregate amount of \$66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was \$50.0 million. As of March 31, 2010, the escrow fund, which has subsequently accrued interest, contained \$52 million. The Company is also entitled to seek direct personal recourse against certain principal shareholders of Blackstone after all monies on deposit in the escrow fund have been paid out or released or are the subject of pending or unresolved indemnification claims but only for a period of six years from the closing date of the merger and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

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

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 the Company from these matters will not exceed the amount of the escrow fund. Expenses incurred by the Company relating to the above matters are recorded as an escrow receivable in the Company's financial statements to the extent the Company believes, among other things, that collection of the claims

is reasonably assured. Expenditures related to such matters for which the Company believes collection is doubtful are recognized in earnings when incurred. As of March 31, 2010 and December 31, 2009, included in Prepaid expenses and other current assets is approximately \$13.4 million and \$12.9 million, respectively, of escrow receivable balances related to the Blackstone matters described above. These amounts include, among other things, attorneys' fees and costs related to the government investigations manifested by the subpoenas described above, the stock option-related claims described above, and costs related to the qui tam actions described above. As described above, some of these reimbursement claims are being contested by the representative of the former shareholders of Blackstone. To mitigate the risk that some reimbursement claims will not be collected, the Company records a reserve against the escrow receivable during the period in which reimbursement claims are recognized.

Table of Contents

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

On or about April 10, 2009, the Company received a HIPAA subpoena ("HIPAA subpoena") issued by the US Attorney's Office for the District of Massachusetts (the "Boston USAO"). The subpoena sought documents concerning, among other things, the Company's promotion and marketing of its bone growth stimulator devices. The Boston USAO issued a supplemental subpoena in this matter dated July 23, 2009, requiring testimony. That office later excused performance with the July 23, 2009 subpoena indefinitely. The Boston USAO also issued supplemental subpoenas in this matter, dated September 21, 2009 and December 16, 2009, respectively, seeking documents. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. Document production in response to the subpoenas is ongoing. On December 21, 2009, the Boston USAO provided the Company with grand jury subpoenas for the testimony of certain current employees in connection with its ongoing investigation. The Company intends to cooperate with the government's requests. In meetings with the Company and its attorneys regarding this matter, the Boston USAO has informed the Company that it is investigating possible criminal and civil violations of federal law related to the Company's promotion and marketing of its bone growth stimulator devices.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the U.S. District Court for the District of Massachusetts against 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. The Company and Orthofix, Inc. were served on or about September 8, 2009. 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 U.S. 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 complaint alleges violations of the False Claims Act, fraudulent billing, illegal kickbacks and wrongful termination based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products, 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 complaint also alleges that TRICARE has been reimbursing the Company for its Cervical Stim® product without approval to do so. An amended complaint alleges conspiracy and

violations of the Sherman Anti-Trust Act in connection with the same alleged conduct. The Company was served with the complaint on or about September 9, 2009. The Company intends to defend vigorously against this lawsuit.

Table of Contents

Our subsidiary, Breg, Inc., was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008, when the product line was divested. As between 2008 and present, numerous product liability cases have been filed in the United States alleging that the local anesthetic, when dispensed by such infusion pumps inside a joint, causes a rare arthritic condition called “chondrolysis.” The Company believes that meritorious defenses exist to these claims and Breg, Inc. intends to vigorously defend these cases.

On April 22, 2010, the Company obtained a copy of a complaint filed by NuVasive, Inc. (“NuVasive”) and Osiris Therapeutics, Inc. (“Osiris”) in the U.S. District Court for the District of New Jersey against Orthofix International N.V., Orthofix, Inc., Orthofix Holdings, Inc., Orthofix Biologics, Orthofix Spinal Implants, and Musculoskeletal Transplant Foundation. The complaint alleges that the Company’s Trinity® Evolution™ allograft product infringes a U.S. patent owned by Osiris and licensed to NuVasive. The complaint requests the court to enjoin the sale of Trinity® Evolution™ and award damages to NuVasive and Osiris for the alleged infringement. The Company believes that it has meritorious defenses to the claims alleged and the Company intends to defend vigorously against this lawsuit.

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. To the extent losses related to these contingencies are both probable and estimable, the Company provides appropriate amounts in the accompanying financial statements.

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, 2009.

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Item 6. Exhibits

a) Exhibits

| Exhibit Number | Description |
|----------------|---|
| 2.1 | Asset Purchase Agreement, dated as of March 8, 2010, by and between Tyco Healthcare Group LP d/b/a Covidien, Covidien AG, Mallinckrodt do Brasil Ltda, Kendall de Mexico S.A. de C.V., Novamedix Limited, Novamedix Distribution Limited, Novamedix Services Limited, Promeca S.A. de C.V., Orthofix do Brasil, Orthofix S.r.l., Orthofix S.A., Intavent Orthofix Limited, Breg Mexico S. de R.I. de CV, and Implantes y Sistemas Medicos, Inc. (filed as an exhibit to the Company's current report on Form 8-K filed March 9, 2010 and incorporated herein by reference). |
| 3.1 | Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference). |
| 3.2 | Articles of Association of the Company as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference). |
| 10.1 | Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference). |
| 10.2 | Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference). |
| 10.3 | 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).

Table of Contents

| | |
|-------|---|
| 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). |
| 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 | Employment Agreement dated April 15, 2005 between Orthofix Inc. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed April 18, 2005 and incorporated herein by reference). |
| 10.14 | 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). |
| 10.15 | 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). |
| 10.16 | 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 | Letter Agreement, dated July 25, 2009, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference). |
| 10.18 | Letter Agreement, dated January 29, 2010, 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, 2009 and incorporated herein by reference). |
| 10.19 | 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.

10.20 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).

10.21* Second Amendment to Credit Agreement, dated February 24, 2010, 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.

10.22 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).

Table of Contents

| | |
|---------------|---|
| <u>10.23*</u> | Description of Director Fee Policy. |
| 10.24 | 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). |
| 10.25 | 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). |
| 10.26 | 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). |
| 10.27 | 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). |
| 10.28 | 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). |
| 10.29+ | 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). |
| 10.30 | 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). |
| 10.31 | 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). |
| 10.32 | 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). |
| 10.33 | 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). |
| 10.34 | |

Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).

10.35 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).

Table of Contents

- 10.36 Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.37 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).
- 10.38 Amendment No. 1 to Amended and Restated Employment Agreement, dated July 31, 2009, by and between Orthofix Inc. and Bradley R. Mason (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.39 Amended and Restated Employment Agreement, entered into on October 23, 2009 and effective as of November 1, 2009, by and between Orthofix Inc. and Bradley R. Mason (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.40 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).
- 10.41 Amendment No. 1 to Amended and Restated Employment Agreement, dated August 4, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.42 Form of Amendment to Stock Option Agreements (for Alan W. Milinazzo, Robert S. Vaters, Bradley R. Mason, Michael M. Finegan and Michael Simpson) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.43 Inducement Stock Option Agreement between Orthofix International N.V. and Kevin L. Unger, dated August 17, 2009 (filed as an exhibit to the Company's current report on Form 8-K filed August 17, 2009 and incorporated herein by reference).
- 10.44 Amended and Restated Employment Agreement, entered into on September 4, 2009, by and between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company's current report on Form 8-K filed September 11, 2009 and incorporated herein by reference).
- 10.45 Amended and Restated Employment Agreement, entered into on July 1, 2009, by and between Orthofix Inc. and Eric Brown (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).

- 10.46 Amended and Restated Employment Agreement, entered into on November 16, 2009, by and between Breg Inc. and Brad Lee (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
- 10.47+ Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).

Table of Contents

31.1* Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.

31.2* Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.

32.1* Section 1350 Certification of Chief Executive Officer.

32.2* Section 1350 Certification of Chief Financial Officer.

* Filed herewith.

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

Table of Contents

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: April 29, 2010

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

Date: April 29, 2010

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