

ORTHOFIX INTERNATIONAL N V  
Form 10-Q  
November 09, 2006

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

**FORM 10-Q**

**(Mark one)**

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

For the quarterly period ended September 30, 2006

OR

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

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

Commission File Number: 0-19961

**ORTHOFIX INTERNATIONAL N.V.**

(Exact name of registrant as specified in its charter)

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

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

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

N/A  
(Zip Code)

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

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

Yes ☒ No ☐

Indicate by check mark whether the registrant 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 ☐

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

As of November 6, 2006, 16,392,959 shares of common stock were issued and outstanding.

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## Forward-Looking Statements

This Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, which relate to our business and financial outlook and which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” or “continue” or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any such statement to reflect new information, the occurrence of future events or circumstances or otherwise.

Factors that could cause actual results to differ materially from those indicated by the forward-looking statements or that could contribute to such differences include, but are not limited to, unanticipated expenditures, changing relationships with customers, suppliers and strategic partners, unfavorable results in litigation matters, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, changes to governmental regulation of medical devices, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry and the economy, currency or interest rate fluctuations and the other risks described under Item 1A - “Business - Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 and Part II, Item 1A - “Risk Factors” in this Form 10-Q.

Table of Contents**PART I****FINANCIAL INFORMATION****Item 1. Condensed Financial Statements****CONDENSED CONSOLIDATED BALANCE SHEETS**

(U.S. Dollars, in thousands except share data and per share date)

|                                                                                                                   | <b>September 30,<br/>2006</b> | <b>December 31,<br/>2005</b> |
|-------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------------------|
|                                                                                                                   | (Unaudited)                   | (Note 2)                     |
| <b>Assets</b>                                                                                                     |                               |                              |
| Current assets:                                                                                                   |                               |                              |
| Cash and cash equivalents                                                                                         | \$ 37,114                     | \$ 63,786                    |
| Restricted cash                                                                                                   | 19,524                        | 13,762                       |
| Trade accounts receivable, net                                                                                    | 102,248                       | 80,745                       |
| Inventories, net                                                                                                  | 63,925                        | 32,853                       |
| Deferred income taxes                                                                                             | 5,405                         | 4,511                        |
| Prepaid expenses and other current assets                                                                         | 18,880                        | 11,618                       |
| Total current assets                                                                                              | 247,096                       | 207,275                      |
| Securities and other investments                                                                                  | 4,082                         | 4,082                        |
| Property, plant and equipment, net                                                                                | 22,917                        | 18,987                       |
| Patents and other intangible assets, net                                                                          | 261,943                       | 65,585                       |
| Goodwill                                                                                                          | 329,577                       | 174,738                      |
| Deferred taxes and other long-term assets                                                                         | 16,287                        | 3,194                        |
| Total assets                                                                                                      | \$ 881,902                    | \$ 473,861                   |
| <b>Liabilities and shareholders' equity</b>                                                                       |                               |                              |
| Current liabilities:                                                                                              |                               |                              |
| Bank borrowings                                                                                                   | \$ 3,109                      | \$ 79                        |
| Current portion of long-term debt                                                                                 | 3,301                         | 15,187                       |
| Trade accounts payable                                                                                            | 19,699                        | 11,602                       |
| Other current liabilities                                                                                         | 40,510                        | 51,208                       |
| Total current liabilities                                                                                         | 66,619                        | 78,076                       |
| Long-term debt                                                                                                    | 326,868                       | 21                           |
| Deferred income taxes                                                                                             | 109,608                       | 25,652                       |
| Other long-term liabilities                                                                                       | 1,370                         | 1,227                        |
| Total liabilities                                                                                                 | 504,465                       | 104,976                      |
| Contingencies (Note 16)                                                                                           |                               |                              |
| Shareholders' equity:                                                                                             |                               |                              |
| Common shares (16,385,625 and 16,009,249 shares issued at September 30, 2006 and December 31, 2005, respectively) | 1,639                         | 1,602                        |
| Additional paid-in capital                                                                                        | 122,867                       | 106,746                      |
| Retained earnings                                                                                                 | 241,031                       | 255,475                      |
| Accumulated other comprehensive income                                                                            | 11,900                        | 5,062                        |
| Total shareholders' equity                                                                                        | 377,437                       | 368,885                      |
| Total liabilities and shareholders' equity                                                                        | \$ 881,902                    | \$ 473,861                   |

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



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FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2006 AND 2005

| (Unaudited, U.S. Dollars, in<br>thousands except share and per<br>share data) | Three Months Ended |            | Nine Months Ended |            |
|-------------------------------------------------------------------------------|--------------------|------------|-------------------|------------|
|                                                                               | 2006               | 2005       | 2006              | 2005       |
| Net sales                                                                     | \$ 83,368          | \$ 75,812  | \$ 249,219        | \$ 233,040 |
| Cost of sales                                                                 | 21,007             | 20,193     | 63,665            | 61,864     |
| Gross profit                                                                  | 62,361             | 55,619     | 185,554           | 171,176    |
| Operating expenses                                                            |                    |            |                   |            |
| Sales and marketing                                                           | 36,277             | 29,148     | 98,985            | 85,373     |
| General and administrative                                                    | 11,747             | 8,431      | 36,337            | 25,706     |
| Research and development                                                      | 42,865             | 2,595      | 48,550            | 8,677      |
| Amortization of intangible assets                                             | 1,929              | 1,635      | 5,408             | 4,923      |
|                                                                               | 92,818             | 41,809     | 189,280           | 124,679    |
| Operating income (loss)                                                       | (30,457)           | 13,810     | (3,726)           | 46,497     |
| Interest income (expense), net                                                | (482)              | (1,160)    | 164               | (3,721)    |
| Other income (expense), net                                                   | (508)              | 73         | (753)             | 1,508      |
| KCI settlement, net of related costs                                          | 0                  | 40,860     | 1,093             | 40,355     |
| Income (loss) before income tax                                               | (31,447)           | 53,583     | (3,222)           | 84,639     |
| Income tax expense                                                            | (3,970)            | (7,563)    | (11,221)          | (18,434)   |
| Net income (loss)                                                             | \$ (35,417)        | \$ 46,020  | \$ (14,443)       | \$ 66,205  |
| Net income (loss) per common share                                            |                    |            |                   |            |
| - basic                                                                       | \$ (2.19)          | \$ 2.88    | \$ (0.90)         | \$ 4.17    |
| Net income (loss) per common share                                            |                    |            |                   |            |
| - diluted                                                                     | \$ (2.17)          | \$ 2.81    | \$ (0.89)         | \$ 4.07    |
| Weighted average number of<br>common shares - basic                           | 16,193,086         | 15,986,599 | 16,084,388        | 15,881,902 |
| Weighted average number of<br>common shares - diluted                         | 16,322,827         | 16,384,106 | 16,229,221        | 16,279,724 |

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

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FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2006 AND 2005

(Unaudited, U.S. Dollars, in thousands)

|                                                                                                    | 2006        | 2005      |
|----------------------------------------------------------------------------------------------------|-------------|-----------|
| Cash flows from operating activities:                                                              |             |           |
| Net income (loss)                                                                                  | \$ (14,443) | \$ 66,205 |
| Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities: |             |           |
| Depreciation and amortization                                                                      | 10,937      | 10,254    |
| Amortization of debt costs                                                                         | 316         | 722       |
| Deferred royalty income                                                                            | --          | (2,443)   |
| Acquired in process research and development                                                       | 40,000      | --        |
| Provision for doubtful accounts                                                                    | 4,330       | 3,279     |
| Tax benefit on non-qualified stock options                                                         | --          | 1,307     |
| Deferred taxes                                                                                     | (8,808)     | (1,580)   |
| Share based compensation                                                                           | 4,980       | 441       |
| Other                                                                                              | 1,398       | 1,945     |
| Change in operating assets and liabilities:                                                        |             |           |
| Restricted cash                                                                                    | (5,762)     | 2,985     |
| Accounts receivable                                                                                | (7,397)     | (11,653)  |
| Inventories                                                                                        | (7,621)     | (4,221)   |
| Prepaid expenses and other                                                                         | (4,994)     | (3,211)   |
| Accounts payable                                                                                   | 7,551       | 270       |
| Current liabilities                                                                                | (29,882)    | 30,488    |
| Net cash (used in) provided by operating activities                                                | (9,395)     | 94,788    |
| Cash flows from investing activities:                                                              |             |           |
| Investments in affiliates and subsidiaries                                                         | (336,808)   | --        |
| Capital expenditures                                                                               | (6,769)     | (8,928)   |
| Net cash used in investing activities                                                              | (343,577)   | (8,928)   |
| Cash flows from financing activities:                                                              |             |           |
| Net proceeds from issuance of common stock                                                         | 11,172      | 6,367     |
| Tax benefit on non-qualified stock options                                                         | 2,048       | --        |
| Repayment of loans and borrowings                                                                  | (15,039)    | (24,199)  |
| Payment of debt issuance costs                                                                     | (5,708)     | --        |
| Proceeds from loans and borrowings                                                                 | 333,048     | 139       |
| Net cash provided by (used in) financing activities                                                | 325,521     | (17,693)  |
| Effect of exchange rate changes on cash                                                            | 779         | (637)     |
| Net (decrease) increase in cash and cash equivalents                                               | (26,672)    | 67,530    |
| Cash and cash equivalents at the beginning of the year                                             | 63,786      | 25,944    |
| Cash and cash equivalents at the end of the period                                                 | \$ 37,114   | \$ 93,474 |

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

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NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: BUSINESS

Orthofix International N.V. (the “Company”) is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical equipment, principally for the orthopedic products market.

NOTE 2: BASIS OF PRESENTATION

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures, normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States, have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. The balance sheet at December 31, 2005 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. For further information, refer to the Consolidated Financial Statements and Notes thereto of our Annual Report on Form 10-K for the year ended December 31, 2005.

NOTE 3: RECENTLY ISSUED ACCOUNTING STANDARDS

In September 2006, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 157, Fair Value Measurements. This Statement defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosure related to the use of fair value measures in financial statements. The Statement is to be effective for the Company’s financial statements issued in 2008; however, earlier application is encouraged. The Company is currently evaluating the timing of adoption and the impact that adoption might have on its financial position or results of operations.

In September 2006, the Securities and Exchange Commission (“SEC”) issued Staff Accounting Bulletin No. 108 (“SAB 108”). Due to diversity in practice among registrants, SAB 108 expresses SEC staff views regarding the process by which misstatements in financial statements are evaluated for purposes of determining whether financial statement restatement is necessary. SAB 108 is effective for fiscal years ending after November 15, 2006, and early application is encouraged. The Company does not believe SAB 108 will have a material impact on its financial position or results from operations.

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109 (“FIN 48”), which clarifies the accounting for uncertainty in income tax positions. This Interpretation requires that the Company recognize in the consolidated financial statements the impact of a tax position that is more likely than not to be sustained upon examination based on the technical merits of the position. The provisions of FIN 48 will be effective as of the beginning of the Company’s 2007 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on the consolidated financial statements.

In June 2006, the FASB ratified Emerging Issues Task Force (“EITF”) Issue No. 06-3, How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation). This standard allows companies to present in their statements of income any taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer, such as sales, use, value-added, and some excise taxes, on either a gross (included in revenue and costs) or a net (excluded from revenue) basis. This standard is effective for interim and fiscal years beginning after December 15, 2006. The Company is currently evaluating the potential impact of this issue on the financial statements, but does not believe the impact of the adoption of this standard will be material.

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In February 2006, the FASB issued SFAS No. 155, Accounting for Certain Hybrid Instruments, which is an amendment to SFAS No. 133 and SFAS No. 140. SFAS No. 155 allows financial instruments which have embedded derivatives to be accounted for as a whole (eliminating the need to bifurcate the derivative from its host) if the holder elects to account for the instrument as a whole instrument on a fair value basis. This statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The Company does not believe the adoption of this statement will have a material impact on the financial statements.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections, which is a replacement of APB Opinion No. 20, Accounting Changes, and SFAS No. 3, Reporting Accounting Changes in Interim Financial Statements. Among other changes, SFAS No. 154 requires that a voluntary change in accounting principle be applied retrospectively such that all prior period financial statements are presented in accordance with the new accounting principle, unless impracticable to do so. SFAS No. 154 also provides that (1) a change in method of depreciating or amortizing a long-lived nonfinancial asset be accounted for as a change in estimate (prospectively) that was effected by a change in accounting principle, and (2) correction of errors in previously issued financial statements should be termed a "restatement". SFAS No. 154 is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 did not have a material impact on the financial statements.

In December 2004, the FASB issued SFAS No. 123 (R), Share-Based Payment, a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. SFAS No. 123 (R) also supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees and amends SFAS No. 95, Statement of Cash Flows. The revision required companies to recognize compensation costs in the income statement based on the fair value of the equity or liability instruments issued and to report the benefits of tax deductions in excess of recognized compensation cost as a financing cash flow rather than as an operating cash flow as reported in the accompanying consolidated statements of cash flows. SFAS No. 123 (R) covers a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. The Company adopted SFAS No. 123 (R) effective January 1, 2006 using the "modified prospective" method. Under the modified prospective method, compensation cost is recognized in the income statement beginning with the effective date, based on the requirements of SFAS No. 123 (R) for all share-based payments granted after that date, and based on the requirements of SFAS 123 for all unvested awards granted prior to the effective date of SFAS No.123 (R). The adoption of SFAS No.123 (R)'s fair value method had a significant impact on the Company's results of operations. See Note 4 "Stock-Based Compensation".

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NOTE 4:

STOCK-BASED COMPENSATION

Prior to January 1, 2006, the Company accounted for stock based compensation plans under the recognition and measurement provisions of APB Opinion No. 25, Accounting for Stock Issued to Employee, and related Interpretations, as permitted by SFAS No. 123, Accounting for Stock-Based Compensation. Stock-based employee compensation expense was recognized relating to options granted at exercise prices lower than the fair market value of the underlying stock on the date of the grant.

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123(R), Share-Based Payment, using the modified prospective transition method. Under this transition method, compensation cost recognized in the first quarter of 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). The fair value of stock options is determined using the Black-Scholes valuation model, which is consistent with our valuation techniques previously utilized for options in footnote disclosures required under SFAS No. 123. Such value is recognized as expense over the service period net of estimated forfeitures. Results for prior periods have not been restated. During the nine months ended September 30, 2006, options were valued at risk-free interest rates between 4.35% and 5.07%, expected volatility of 33.4%, expected term of 4.3 years and a dividend rate of zero.

As a result of adopting SFAS No. 123(R) on January 1, 2006 the Company's income before income taxes and net income for the three months ended September 30, 2006, are \$1.3 million and \$0.9 million lower, respectively, than if it had continued to account for share-based compensation under APB 25. For the nine month period ended September 30, 2006, the Company's income before income taxes and net income are \$4.9 million and \$3.5 million lower, respectively, than if it had continued to account for share-based compensation under APB 25. Basic and diluted earnings per share for the three months ended September 30, 2006 would have been \$0.07 and \$0.08 higher, respectively, if the Company had not adopted SFAS No. 123(R). Basic and diluted earnings per share for the nine months ended September 30, 2006 would have each been \$0.22 higher if the Company had not adopted SFAS No. 123(R). As of September 30, 2006, the compensation expense relating to options already granted and expected to be recognized is \$14.2 million. This expense is expected to be recognized over a weighted average period of 1.59 years.

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The following table shows the detail of stock-based compensation by line item in the Condensed Consolidated Statements of Income for the three and nine months ended September 30, 2006:

| <b>(In thousands)</b>          | <b>Three Months<br/>Ended<br/>September 30,<br/>2006</b> | <b>Nine Months<br/>Ended<br/>September 30,<br/>2006</b> |
|--------------------------------|----------------------------------------------------------|---------------------------------------------------------|
| Cost of sales                  | \$ 83                                                    | \$ 151                                                  |
| Sales and marketing            | 472                                                      | 882                                                     |
| General and administrative (1) | 691                                                      | 3,639                                                   |
| Research and development       | 64                                                       | 247                                                     |
| <b>Total</b>                   | <b>\$ 1,310</b>                                          | <b>\$ 4,919</b>                                         |

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(1) Amount includes \$656 of stock-based compensation from the accelerated vesting of options associated with the transition of senior management in the first quarter of 2006.

Prior to the adoption of SFAS No. 123(R), the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the Statement of Cash Flows. SFAS No. 123(R) requires the cash flows resulting from the tax benefits resulting from the tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows. The \$2.0 million excess tax benefit classified as a financing cash inflow, in the nine months ended September 30, 2006, would have been classified as an operating cash inflow had the Company not adopted SFAS No. 123(R).

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The following table illustrates the effect on net income and earnings per share if the fair value based method had been applied to all stock-based awards granted for all periods presented.

| (In thousands, except per share data)                                                                               | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |           |
|---------------------------------------------------------------------------------------------------------------------|-------------------------------------|-----------|------------------------------------|-----------|
|                                                                                                                     | 2006                                | 2005      | 2006                               | 2005      |
| Net income (loss)                                                                                                   |                                     |           |                                    |           |
| As reported                                                                                                         | \$ (35,417)                         | \$ 46,020 | \$ (14,443)                        | \$ 66,205 |
| Add: Stock-based employee compensation expense included in reported net income, net of related tax effects          | 938                                 | 87        | 3,469                              | 261       |
| Less: Total stock-based employee compensation expense determined under fair value method for all awards, net of tax | (938)                               | (906)     | (3,469)                            | (2,189)   |
| Pro forma                                                                                                           | \$ (35,417)                         | \$ 45,201 | \$ (14,443)                        | \$ 64,277 |
| Net income per common share - basic                                                                                 |                                     |           |                                    |           |
| As reported                                                                                                         | \$ (2.19)                           | \$ 2.88   | \$ (0.90)                          | \$ 4.17   |
| Pro forma                                                                                                           | \$ (2.19)                           | \$ 2.83   | \$ (0.90)                          | \$ 4.05   |
| Net income per common share - diluted                                                                               |                                     |           |                                    |           |
| As reported                                                                                                         | \$ (2.17)                           | \$ 2.81   | \$ (0.89)                          | \$ 4.07   |
| Pro forma                                                                                                           | \$ (2.17)                           | \$ 2.76   | \$ (0.89)                          | \$ 3.95   |

## NOTE 5:

## RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform to the 2006 presentation. The reclassifications have no effect on previously reported net income or shareholders' equity.

## NOTE 6:

## INVENTORY

Inventories are valued at the lower of cost or estimated net realizable value, after provision for excess or obsolete items. Cost is determined on a weighted-average basis, which approximates the FIFO method. The valuation of work-in-process, finished goods, field inventory and consignment inventory includes the cost of materials, labor and production. Field inventory represents immediately saleable finished goods inventory that is in the possession of the Company's direct sales representatives.

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Inventories were as follows:

| (In thousands)                       | September 30,<br>2006 | December 31,<br>2005 |
|--------------------------------------|-----------------------|----------------------|
| Raw materials                        | \$ 7,867              | \$ 7,242             |
| Work-in-process                      | 5,798                 | 3,344                |
| Finished goods                       | 36,137                | 11,538               |
| Field inventory (as described above) | 6,492                 | 7,404                |
| Consignment inventory                | 12,676                | 6,659                |
| Less reserve for obsolescence        | (5,045)               | (3,334)              |
|                                      | \$ 63,925             | \$ 32,853            |

## NOTE 7:

## ACQUISITIONS

On September 22, 2006, the Company purchased 100% of the stock of Blackstone Medical, Inc. ("Blackstone") for a purchase price of \$333.0 million plus acquisition costs and is subject to certain closing adjustments. The acquisition and related costs were financed with \$330.0 million of senior secured bank debt and cash on hand. Blackstone, based in Springfield, Massachusetts, specializes in the design, development and marketing of spinal implant and related biologic products. Blackstone's product lines include spinal fixating devices including hooks, rods, screws, plates, various spacers and cages and related biologics products. Blackstone generated \$62.1 million in net revenues for the period January 1, 2006 to September 22, 2006.

The Company considered this acquisition as a way to fortify and further advance its business strategy to expand its spinal sector. The acquisition broadened the Company's product lines, reduced reliance on the success of any single product and enlarged channel opportunities for products from both companies.

Factors that contributed to the valuation of Blackstone included the recognition that Blackstone had established itself as what the Company believes to be one of the largest private spine companies with a broad portfolio of spinal product offerings. Further, Blackstone has a strong brand name and product identity in the spinal industry. Blackstone has a history of sales and earnings growth that compares favorably to the fast growing spinal market that its product lines serve. Orthofix valued Blackstone after reviewing a range of valuation methodologies provided by its financial advisors for the transaction, including comparable publicly-traded companies, comparable precedent transactions, discounted cash flow analysis and comparison to Orthofix's trading multiples. The resulting purchase price of Blackstone exceeded the value of the net assets acquired.

The acquisition has been accounted for using the purchase method in accordance with SFAS No. 141, Business Combinations. The purchase price has been preliminarily allocated to the assets acquired and liabilities assumed based on their estimated fair market value at the date of acquisition.

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A preliminary allocation of the purchase price reflects the following:

(In thousands)

|                                                         |    |          |
|---------------------------------------------------------|----|----------|
| Working capital, other than cash                        | \$ | 25,041   |
| Fixed assets acquired                                   |    | 2,953    |
| Identifiable intangible assets (definite lived)         |    | 124,503  |
| Identifiable intangible assets (indefinite lived)       |    | 77,000   |
| Deferred tax liability                                  |    | (83,935) |
| In-process research and development                     |    | 40,000   |
| Goodwill                                                |    | 150,865  |
| Preliminary purchase price, including acquisition costs | \$ | 336,427  |

The purchase price has been allocated to assets acquired, purchased in-process research and development, and liabilities assumed based on their estimated fair value at the acquisition date. The amount of the purchase price allocated to purchased in-process research and development was written off at the date of acquisition and resulted in a charge of \$40.0 million. This charge is included in the research and development expense line item on the Condensed Consolidated Statements of Income (Loss) and included the Dynamic Stabilization and Cervical Disk which together accounted for 93% of the fair value. The fair value of the in-process research and development was estimated using the discounted earnings method. The amount written off as purchased in-process research and development is not deductible for income tax purposes in the United States. The purchase price for the acquisition is subject to potential upward or downward adjustments based on the difference between the estimated and final working capital of Blackstone, as defined in the agreement and plan of merger. In addition, other items that may affect the final purchase price allocation include finalization of acquisition costs, revisions to tangible and intangible assets based on final appraisals and other information that provides a better estimate of the fair value of the assets acquired and the liabilities assumed.

There are no residual values for any of the intangible assets subject to amortization acquired during the Blackstone acquisition. Definite lived intangible assets acquired in the Blackstone acquisition consist of:

(Dollar amounts in thousands)

|                                        | <b>Fair value at<br/>Acquisition</b> | <b>Remaining<br/>Useful Life</b> |
|----------------------------------------|--------------------------------------|----------------------------------|
| Top six distributor relationships      | \$ 28,000                            | 12 Years                         |
| All other distributor relationships    | 25,000                               | 16 Years                         |
| Technology                             | 71,000                               | 13 Years                         |
| Total definite lived intangible assets | \$ 124,000                           |                                  |

The Company has determined that trademarks acquired during the Blackstone acquisition, valued at \$77.0 million, are indefinite lived intangible assets. The Company considered the criteria prescribed by paragraphs 11 (a), (c), (e) and (f) of SFAS 142 in determining that registered trademarks acquired during the Blackstone acquisition have an indefinite life. The Company is not aware of any legal, regulatory, or contractual provisions that limit the useful lives of these registered trademarks. The Company does not believe the effects of obsolescence, demand, competition, or other economic factors will cause the useful lives of these registered trademarks to be limited. The Company concluded that no legal, regulatory, contractual, competitive, economic, or other factors limit the useful life of the registered trademarks to the Company, and therefore the useful lives of the registered trademarks are considered to be indefinite.

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The summary pro forma condensed unaudited results of operations and earnings per share for the three and nine month periods ended September 30, 2006 and 2005, assuming consummation of the Blackstone acquisition as of January 1, 2005 and January 1, 2006, are as follows:

| (In thousands except per share data) | Three Months Ended<br>September 30, 2006 |            | Three Months Ended<br>September 30, 2005 |           |
|--------------------------------------|------------------------------------------|------------|------------------------------------------|-----------|
|                                      | As Reported                              | Pro Forma  | As Reported                              | Pro Forma |
| Net sales                            | \$ 83,368                                | \$ 104,684 | \$ 75,812                                | \$ 90,244 |
| Net income (loss)                    | \$ (35,417)                              | \$ (1,363) | \$ 46,020                                | \$ 39,895 |
| Per share data:                      |                                          |            |                                          |           |
| Basic                                | \$ (2.19)                                | \$ (0.08)  | \$ 2.88                                  | \$ 2.50   |
| Diluted                              | \$ (2.17)                                | \$ (0.08)  | \$ 2.81                                  | \$ 2.43   |

| (In thousands except per share data) | Nine Months Ended<br>September 30, 2006 |            | Nine Months Ended<br>September 30, 2005 |            |
|--------------------------------------|-----------------------------------------|------------|-----------------------------------------|------------|
|                                      | As Reported                             | Pro Forma  | As Reported                             | Pro Forma  |
| Net sales                            | \$ 249,219                              | \$ 311,360 | \$ 233,040                              | \$ 276,577 |
| Net income (loss)                    | \$ (14,443)                             | \$ 9,425   | \$ 66,205                               | \$ 48,307  |
| Per share data:                      |                                         |            |                                         |            |
| Basic                                | \$ (0.90)                               | \$ 0.59    | \$ 4.17                                 | \$ 3.04    |
| Diluted                              | \$ (0.89)                               | \$ 0.58    | \$ 4.07                                 | \$ 2.97    |

In-process research and development charge of \$40.0 million recorded during the three and nine months ended September, 30, 2006 has been excluded from the pro forma financial information.

In February 2006, the Company purchased 52% of International Medical Supplies Distribution GmbH ("IMES"), a German distributor of Breg products, for approximately \$1.1 million in cash. The preliminary purchase price allocation included approximately \$1.1 million of goodwill. The operations of the acquired distributor are included in the Company's statement of operations from the date of acquisition. Management will complete the purchase price allocation in 2006.

## NOTE 8:

## GOODWILL

The change in the net carrying value of goodwill for the period ended September 30, 2006 is as follows:

## (In thousands)

|                       | Americas<br>Orthofix | Americas<br>Breg | Americas<br>Blackstone | International<br>Orthofix | Total      |
|-----------------------|----------------------|------------------|------------------------|---------------------------|------------|
| At December 31, 2005  | \$ 32,916            | \$ 101,322       | \$ -                   | \$ 40,500                 | \$ 174,738 |
| Acquisition           | -                    | -                | 150,865                | 1,108                     | 151,973    |
| Foreign Currency      | (41)                 | -                | -                      | 2,907                     | 2,866      |
| At September 30, 2006 | \$ 32,875            | \$ 101,322       | \$ 150,865             | \$ 44,515                 | \$ 329,577 |

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## NOTE 9:

## LONG TERM DEBT

| (In thousands)        | September 30,<br>2006 | December 31, 2005 |
|-----------------------|-----------------------|-------------------|
| Long-term obligations | \$ 330,000            | \$ 14,750         |
| Other loans           | 169                   | 458               |
|                       | 330,169               | 15,208            |
| Less current portion  | (3,301)               | (15,187)          |
|                       | \$ 326,868            | \$ 21             |

On September 22, 2006 our wholly-owned US holding company subsidiary, Orthofix Holdings, Inc. ("Orthofix Holdings"), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million, the proceeds of which, together with cash balances were used for payment of the purchase price of Blackstone; and (2) a six-year revolving credit facility of \$45.0 million. As of September 30, 2006 and as of November 6, 2006 we had no amounts outstanding under the revolving credit facility and \$330.0 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of LIBOR or prime rate plus a margin, currently LIBOR plus 1.75%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. The effective interest rate as of September 30, 2006 on the senior secured debt is 7.12%.

The Company, certain foreign subsidiaries of the Company, including Victory Medical Limited (Orthofix Holdings's immediate parent) and Colgate Medical Limited (Victory Medical Limited's immediate parent), and each of Orthofix Holdings's direct and indirect subsidiaries, including Orthofix Inc., Breg and Blackstone, have guaranteed the obligations of Orthofix Holdings under the senior secured credit facility. The obligations of Orthofix Holdings under the senior secured bank facility and the guarantors under their guarantees are secured by the pledge of their respective assets located in the United States. The senior secured bank facility restricts the Company's, Colgate Medical Limited's and Victory Medical Limited's access to the funds borrowed under the credit facility. Orthofix Holdings and its subsidiaries that are the guarantors may have access to the funds borrowed under the credit facility for operational purposes.

## NOTE 10:

## COMMON SHARES

For the nine months ended September 30, 2006, the Company issued 376,376 shares of common stock upon the exercise of outstanding stock options and shares issued pursuant to the Company's employee stock purchase plan for proceeds of \$11.2 million.

## NOTE 11:

## COMPREHENSIVE INCOME (LOSS)

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

| (In thousands)                          | Accumulated Other<br>Comprehensive<br>Income |
|-----------------------------------------|----------------------------------------------|
| Balance at December 31, 2005            | \$ 5,062                                     |
| Foreign currency translation adjustment | 6,838                                        |

|                               |    |        |
|-------------------------------|----|--------|
| Balance at September 30, 2006 | \$ | 11,900 |
|-------------------------------|----|--------|

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| (In thousands)                           | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |           |
|------------------------------------------|-------------------------------------|-----------|------------------------------------|-----------|
|                                          | 2006                                | 2005      | 2006                               | 2005      |
| Net income (loss)                        | \$ (35,417)                         | \$ 46,020 | \$ (14,443)                        | \$ 66,205 |
| Other comprehensive income (loss):       |                                     |           |                                    |           |
| Unrealized gain on derivative instrument | --                                  | 70        | --                                 | 155       |
| Foreign currency translation adjustment  | 397                                 | (499)     | 6,838                              | (8,505)   |
| Total comprehensive income (loss)        | \$ (35,020)                         | \$ 45,591 | \$ (7,605)                         | \$ 57,855 |

## 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.

*Americas Orthofix*

Americas Orthofix operation ("Americas") consists of operations in the United States excluding Breg and Blackstone (each as defined below), Mexico, Brazil, and Puerto Rico. Americas, as defined, uses both direct and distributor sales representatives to sell to hospitals, doctors, and other healthcare providers in the Americas market.

*Americas Breg*

Americas Breg operation ("Breg") consists of 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.

*Americas Blackstone*

Americas Blackstone operation ("Blackstone") consists of Blackstone Medical, Inc. and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Blackstone, based in Springfield, Massachusetts, specializes in the design, development and marketing of spinal implant and related biologic products. Blackstone's operating income (loss) includes amortization of acquired intangible assets and inventory which has been stepped-up in value for the Blackstone acquisition. The operating results for the five business days in the third quarter are not material.

*International Orthofix*

International Orthofix operation ("International") consists of operations which are located in the rest of the world as well as independent distributors. International, as defined, uses both direct and distributor sales representatives to sell Orthofix and Breg products to hospitals, doctors, and other healthcare providers.

*Group Activities*

Group Activities are comprised of the Parent's operating expenses and identifiable assets.

The following table presents external and intersegment sales by segment for the three month period ended September 30:

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| (In thousands)         | External Sales |           | Intersegment Sales |           |
|------------------------|----------------|-----------|--------------------|-----------|
|                        | 2006           | 2005      | 2006               | 2005      |
| Americas Orthofix      | \$ 41,525      | \$ 35,957 | \$ 818             | \$ 300    |
| Americas Breg          | 18,667         | 17,983    | 406                | 102       |
| International Orthofix | 23,176         | 21,875    | 10,072             | 13,289    |
| Total                  | \$ 83,368      | \$ 75,815 | \$ 11,296          | \$ 13,691 |

The following table presents external and intersegment sales by segment for the nine month period ended September 30:

| (In thousands)         | External Sales |            | Intersegment Sales |           |
|------------------------|----------------|------------|--------------------|-----------|
|                        | 2006           | 2005       | 2006               | 2005      |
| Americas Orthofix      | \$ 122,285     | \$ 105,596 | \$ 2,476           | \$ 1,304  |
| Americas Breg          | 55,901         | 53,368     | 1,027              | 365       |
| International Orthofix | 71,033         | 74,076     | 44,218             | 42,192    |
| Total                  | \$ 249,219     | \$ 233,040 | \$ 47,721          | \$ 43,861 |

The following table presents operating income by segment for the three and nine month periods ended September 30:

| Operating Income (Expense)<br>(In thousands) | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |           |
|----------------------------------------------|-------------------------------------|-----------|------------------------------------|-----------|
|                                              | 2006                                | 2005      | 2006                               | 2005      |
| Americas Orthofix                            | \$ 6,877                            | \$ 8,475  | \$ 25,235                          | \$ 25,195 |
| Americas Breg                                | 1,392                               | 1,534     | 4,926                              | 6,881     |
| Americas Blackstone                          | (40,271)                            | -         | (40,271)                           | -         |
| International Orthofix                       | 4,444                               | 5,314     | 15,189                             | 19,237    |
| Group Activities                             | (2,594)                             | (1,298)   | (7,123)                            | (4,056)   |
| Eliminations                                 | (305)                               | (215)     | (1,682)                            | (760)     |
| Total                                        | \$ (30,457)                         | \$ 13,810 | \$ (3,726)                         | \$ 46,497 |

The following table presents identifiable assets by segment, excluding intercompany balances and investments in consolidated subsidiaries.

Table of Contents**Identifiable Assets**

| <b>(In thousands)</b>  | <b>September 30,<br/>2006</b> | <b>December 31,<br/>2005</b> |
|------------------------|-------------------------------|------------------------------|
| Americas Orthofix      | \$ 90,138                     | \$ 112,057                   |
| Americas Breg          | 182,756                       | 185,921                      |
| Americas Blackstone    | 435,968                       | -                            |
| International Orthofix | 138,043                       | 178,682                      |
| Group activities       | 49,747                        | 9,958                        |
| Eliminations           | (14,750)                      | (12,757)                     |
| <b>Total</b>           | <b>\$ 881,902</b>             | <b>\$ 473,861</b>            |

| <b>Sales by Market Sector<br/>for the three month period ended September 30, 2006</b> |                              |                      |                                   |              |               |
|---------------------------------------------------------------------------------------|------------------------------|----------------------|-----------------------------------|--------------|---------------|
| <b>(In thousands)</b>                                                                 | <b>Americas<br/>Orthofix</b> | <b>Americas Breg</b> | <b>International<br/>Orthofix</b> | <b>Total</b> |               |
| Orthopedic                                                                            |                              |                      |                                   |              |               |
| Spine                                                                                 | \$ 29,263                    | \$ -                 | \$ 19                             | \$           | 29,282        |
| Reconstruction                                                                        | 2,761                        | 18,667               | 10,737                            |              | 32,165        |
| Trauma                                                                                | 8,531                        | -                    | 7,270                             |              | 15,801        |
| Total Orthopedic                                                                      | 40,555                       | 18,667               | 18,026                            |              | 77,248        |
| Non-Orthopedic                                                                        | 970                          | -                    | 5,150                             |              | 6,120         |
| <b>Total</b>                                                                          | <b>\$ 41,525</b>             | <b>\$ 18,667</b>     | <b>\$ 23,176</b>                  | <b>\$</b>    | <b>83,368</b> |

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**Sales by Market Sector  
for the three month period ended September 30, 2005**

| <b>(In thousands)</b> | <b>Americas<br/>Orthofix</b> | <b>Americas Breg</b> | <b>International<br/>Orthofix</b> | <b>Total</b> |
|-----------------------|------------------------------|----------------------|-----------------------------------|--------------|
| Orthopedic            |                              |                      |                                   |              |
| Spine                 | \$ 25,422                    | \$ -                 | \$ 26                             | \$ 25,448    |
| Reconstruction        | 1,955                        | 17,983               | 10,062                            | 30,000       |
| Trauma                | 8,092                        | -                    | 6,900                             | 14,992       |
| Total Orthopedic      | 35,469                       | 17,983               | 16,988                            | 70,440       |
| Non-Orthopedic        | 485                          | -                    | 4,887                             | 5,372        |
| Total                 | \$ 35,954                    | \$ 17,983            | \$ 21,875                         | \$ 75,812    |

**Sales by Market Sector  
for the nine month period ended September 30, 2006**

| <b>(In thousands)</b> | <b>Americas<br/>Orthofix</b> | <b>Americas Breg</b> | <b>International<br/>Orthofix</b> | <b>Total</b> |
|-----------------------|------------------------------|----------------------|-----------------------------------|--------------|
| Orthopedic            |                              |                      |                                   |              |
| Spine                 | \$ 86,722                    | \$ -                 | \$ 59                             | \$ 86,781    |
| Reconstruction        | 8,235                        | 55,901               | 32,782                            | 96,918       |
| Trauma                | 24,908                       | -                    | 22,613                            | 47,521       |
| Total Orthopedic      | 119,865                      | 55,901               | 55,454                            | 231,220      |
| Non-Orthopedic        | 2,420                        | -                    | 15,579                            | 17,999       |
| Total                 | \$ 122,285                   | \$ 55,901            | \$ 71,033                         | \$ 249,219   |

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**Sales by Market Sector  
for the nine month period ended September 30, 2005**

| (In thousands)   | Americas<br>Orthofix | Americas Breg | International<br>Orthofix | Total      |
|------------------|----------------------|---------------|---------------------------|------------|
| Orthopedic       |                      |               |                           |            |
| Spine            | \$ 73,752            | \$ -          | \$ 95                     | \$ 73,847  |
| Reconstruction   | 6,270                | 53,368        | 34,737                    | 94,375     |
| Trauma           | 24,345               | -             | 23,230                    | 47,575     |
| Total Orthopedic | 104,367              | 53,368        | 58,062                    | 215,797    |
| Non-Orthopedic   | 1,229                | -             | 16,014                    | 17,243     |
| Total            | \$ 105,596           | \$ 53,368     | \$ 74,076                 | \$ 233,040 |

## NOTE 13:

## INCOME TAXES

The difference between the reported provision for income taxes and a provision computed by applying the statutory rates applicable to each subsidiary of the Company is attributable to the non-deductible \$40.0 million purchased in-process research and development charge associated with the Blackstone acquisition, as described in Note 7, along with a non-recurring discrete tax benefit resulting from the Company's election to adopt a new tax provision in Italy. The election allowed the Company to increase, for tax purposes only, the value of our trademarks in Italy by approximately \$15.0 million. The Company incurred a tax liability of \$2.7 million from applying a 19% tax rate to the revaluation of the trademark value. The Company expects to receive a future tax benefit of \$5.6 million associated with amortization of that step-up in value which is based on the current Italian tax rates of approximately 37%. The net of the \$5.6 million deferred tax asset and the \$2.7 million tax liability resulted in a \$2.9 million non-recurring discrete tax benefit. Further the effective tax rate has been affected by non-deductible foreign losses, the generation of unutilizable net operating losses in various jurisdictions, tax planning associated with the acquisition of Breg and the Section 199 deduction related to income attributable to production activities occurring in the United States.

## NOTE 14:

## EARNINGS PER SHARE

For the three and nine month periods ended September 30, 2006 and 2005, there were no adjustments to net income (the numerators) for purposes of calculating basic and diluted net income per common share. The following table sets forth a reconciliation of the share numbers (the denominators) in computing earnings per share in accordance with SFAS No. 128, Earnings Per Share:

|                                          | Three Months Ended<br>September 30, |            | Nine Months Ended<br>September 30, |            |
|------------------------------------------|-------------------------------------|------------|------------------------------------|------------|
|                                          | 2006                                | 2005       | 2006                               | 2005       |
| Weighted average common shares - basic   | 16,193,086                          | 15,986,599 | 16,084,388                         | 15,881,902 |
| Effect of dilutive securities:           |                                     |            |                                    |            |
| Effect of SFAS No. 123 (R)               | (158,654)                           | --         | (151,745)                          | --         |
| Stock options outstanding                | 288,395                             | 397,507    | 296,578                            | 397,822    |
| Weighted average common shares - diluted | 16,322,827                          | 16,384,106 | 16,229,221                         | 16,279,724 |



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The Company did not include 680,300 options in the treasury method for calculating the diluted shares calculation for both the three and nine month periods ended September 30, 2006, because their inclusion would have been antidilutive or because their exercise price exceeded the average market price of our common stock during the period. For the three and nine month periods ended September 30, 2005, the Company did not include 266,000 and 617,000 options in the treasury method for calculating the diluted shares outstanding because their inclusion would have been antidilutive or because their exercise price exceeded the average market price for our common stock during the period.

NOTE 15:

DERIVATIVE INSTRUMENT

The Company utilizes foreign currency forward contracts to manage its foreign currency exposure related to a portion of the Company's accounts receivable that are denominated in Euros. The strategy of the foreign currency contracts is to neutralize the foreign currency impact on earnings when converting 5.0 million Euros of accounts receivable into U.S. dollars. The conversion of the underlying exposure and the forward contracts offset and had no net impact on earnings in the three and nine month periods ended September 30, 2006. The Company made no cash payments in the third quarter to settle forward contracts. For the nine month period ended September 30, 2006, the Company paid cash of \$385,000 to settle forward contracts. On September 29, 2006, the Company entered into a new forward currency contract to sell 5.0 million Euro at an all-in rate of 1.2733 which was outstanding at September 30, 2006 and will terminate or settle on December 29, 2006. All foreign currency forward contracts entered into in the three or nine months ended September 30, 2006, have been accounted for as fair value hedges in accordance with SFAS No. 133 and the related gains (losses) were recorded in other income and the related tax amounts in taxation.

NOTE 16:

CONTINGENCIES

*Litigation*

The Company, in the normal course of its business, is involved in various lawsuits from time to time and may be subject to certain other contingencies.

In management's opinion, except as discussed below, the Company is not currently involved in any legal proceeding, individually or in the aggregate, that could have a material effect on the financial position, liquidity or operating results of the Company.

The Company's subsidiary, Blackstone Medical, is a defendant in a patent infringement lawsuit captioned *Medtronic Sofamor Danek USA Inc., Warsaw Orthopedic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Sofamor Danek Deggendorf, GmbH v. Blackstone Medical, Inc.*, Civil Action No. 06-30165-MAP, filed on September 22, 2006 in the United States District Court for the District of Massachusetts. The plaintiffs allege that (i) they are the exclusive licensees of United States Patent Nos. 6,926,718 B1, 6,936,050 B2 ( the "Patents"), and (ii) Blackstone Medical's making, selling, offering for sale, and using within the United States its Anterior Cervical Plate and 3° Anterior Cervical Plate products is infringing and has infringed the Patents, and that such infringement has been willful. The Complaint requests both damages and an injunction against further alleged infringement of the Patents. The Complaint does not specifically state an amount of damages. On October 18, 2006, Blackstone Medical filed its Answer and Counterclaims, denying infringement and asserting that the Patents are invalid.

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*Risks and Uncertainties*

As of September 30, 2006, the Company has a Euro denominated intercompany receivable of 48.3 million in an entity with U.S. Dollar functional currency for which there was no offsetting Euro payable. Accordingly, the Company is exposed to potential movements in currency rates between the Euro and the U.S. Dollar. The Company is currently evaluating the options to limit the currency exposure on this Euro denominated receivable.

*Concentrations of credit risk*

There have been no material changes from the information provided in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

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**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion and analysis addresses our liquidity, financial condition, and the results of our operations for the three and nine months ended September 30, 2006 compared to our results of operations for the three and nine months ended September 30, 2005. 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 year ended December 31, 2005.

**General**

We are a diversified orthopedic products company offering a broad line of surgical, as well as non-surgical, products for the Spine, Reconstruction and Trauma 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 non-invasive 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. With the acquisition of Blackstone Medical on September 22, 2006, our main products will now also include spinal implant and biologics products for spinal applications. Our products also include a device for enhancing venous circulation, cold therapy, other pain management products, bone cement used to fix artificial implants and airway management products used in anesthesia applications.

We have administrative and training facilities in the United States, the United Kingdom 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, Ireland, 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 our wholly-owned and majority-owned subsidiaries and entities over which we have control. All intercompany accounts and transactions are eliminated in consolidation. The equity method of accounting is used when we have significant influence over significant operating decisions but do not hold control. Under the equity method, original investments are recorded at cost and adjusted by our share of undistributed earnings or losses of these companies. All material intercompany transactions and profits are eliminated in consolidation.

Our reporting currency is the United States dollar. All balance sheet accounts, except shareholders' equity, are translated at the period end exchange rates, and revenue and expense items are translated at weighted average rates of exchange prevailing during the period. Gains and losses resulting from foreign currency transactions are included in other income (expense). Gains and losses resulting from the translation of foreign currency financial statements are recorded in the accumulated other comprehensive income (loss) component of shareholders' equity.

Our financial condition, results of operations and cash flows are not significantly impacted by seasonal 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. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar income and expenditures. We also use derivative instruments from time to time to hedge foreign currency fluctuation exposures. See Item 3 - "Quantitative

and Qualitative Disclosures About Market Risk.”

On September 22, 2006, we completed the acquisition of privately held Blackstone Medical, Inc. (“Blackstone”), a company specializing in the design, development and marketing of spinal implant and related biologics products. The purchase price for the acquisition was \$333.0 million, subject to certain closing adjustments, plus transaction costs totaling approximately \$4.2 million as of September 30, 2006. Financing costs were approximately \$6.0 million. The acquisition and related costs were financed with \$330.0 million of senior secured bank debt and cash on hand. The Company’s reported third quarter results include the impact of purchase accounting and interest expense associated with the acquisition. Blackstone’s other operating results for the remaining five business days in the third quarter were not material and will be included in the Company’s fourth quarter results.

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Effective with the acquisition of Blackstone, we manage our operations as four business segments: Americas Orthofix, Americas Breg, Americas Blackstone and International Orthofix. Americas Orthofix consists of operations in the United States excluding the operations of Breg and Blackstone, as well as operations in Mexico, Brazil and Puerto Rico. Americas Breg consists of Breg's domestic and independent international distributor operations. Americas Blackstone consists of the recently acquired Blackstone. International Orthofix 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 Parent's operating expenses and identifiable assets.

Table of Contents**Segment and Market Sector Revenues**

Our revenues are generally derived from two primary sources: sales of orthopedic and non-orthopedic products. Orthopedic products are sold into three market sectors, Spine, Reconstruction, and Trauma, which together accounted for 93% of our total net sales in the three and nine months ended September 30, 2006 and 2005. Sales of non-orthopedic products, including the Laryngeal Mask product, woman's care and other products, accounted for 7% of our total net sales in the three and nine months ended September 30, 2006 and 2005.

The following tables display the net sales by business segment and net sales by market sectors for the three and nine months ended September 30, 2006 and 2005. We provide net sales by market sector for information purposes only. We keep our books and records and account for net sales, cost of sales and expenses by business segment.

**Business Segment:**

| (In thousands)         | Three Months Ended September 30, |                            |           |                            |
|------------------------|----------------------------------|----------------------------|-----------|----------------------------|
|                        | 2006                             |                            | 2005      |                            |
|                        | Net Sales                        | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Americas Orthofix      | \$ 41,525                        | 50%                        | \$ 35,954 | 47%                        |
| Americas Breg          | 18,667                           | 22%                        | 17,983    | 24%                        |
| International Orthofix | 23,176                           | 28%                        | 21,875    | 29%                        |
| Total                  | \$ 83,368                        | 100%                       | \$ 75,812 | 100%                       |

| (In thousands)         | Nine Months Ended September 30, |                            |            |                            |
|------------------------|---------------------------------|----------------------------|------------|----------------------------|
|                        | 2006                            |                            | 2005       |                            |
|                        | Net Sales                       | Percent of Total Net Sales | Net Sales  | Percent of Total Net Sales |
| Americas Orthofix      | \$ 122,285                      | 49%                        | \$ 105,596 | 45%                        |
| Americas Breg          | 55,901                          | 22%                        | 53,368     | 23%                        |
| International Orthofix | 71,033                          | 29%                        | 74,076     | 32%                        |
| Total                  | \$ 249,219                      | 100%                       | \$ 233,040 | 100%                       |

Table of Contents**Market Sector:**

| (In thousands)   | Three Months Ended September 30, |                            |           |                            |
|------------------|----------------------------------|----------------------------|-----------|----------------------------|
|                  | 2006                             |                            | 2005      |                            |
|                  | Net Sales                        | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Orthopedic       |                                  |                            |           |                            |
| Spine            | \$ 29,282                        | 35%                        | \$ 25,448 | 34%                        |
| Reconstruction   | 32,165                           | 39%                        | 30,000    | 40%                        |
| Trauma           | 15,801                           | 19%                        | 14,992    | 19%                        |
| Total Orthopedic | 77,248                           | 93%                        | 70,440    | 93%                        |
| Non-Orthopedic   | 6,120                            | 7%                         | 5,372     | 7%                         |
| Total            | \$ 83,368                        | 100%                       | \$ 75,812 | 100%                       |

| (In thousands)   | Nine Months Ended September 30, |                            |            |                            |
|------------------|---------------------------------|----------------------------|------------|----------------------------|
|                  | 2006                            |                            | 2005       |                            |
|                  | Net Sales                       | Percent of Total Net Sales | Net Sales  | Percent of Total Net Sales |
| Orthopedic       |                                 |                            |            |                            |
| Spine            | \$ 86,781                       | 35%                        | \$ 73,847  | 32%                        |
| Reconstruction   | 96,918                          | 39%                        | 94,375     | 41%                        |
| Trauma           | 47,521                          | 19%                        | 47,575     | 20%                        |
| Total Orthopedic | 231,220                         | 93%                        | 215,797    | 93%                        |
| Non-Orthopedic   | 17,999                          | 7%                         | 17,243     | 7%                         |
| Total            | \$ 249,219                      | 100%                       | \$ 233,040 | 100%                       |

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The following table presents certain items from our statements of income as a percentage of net sales for the periods indicated:

|                                   | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-----------------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                                   | <b>2006</b>                                 | <b>2005</b> | <b>2006</b>                                | <b>2005</b> |
|                                   | (%)                                         | (%)         | (%)                                        | (%)         |
| Net sales                         | 100                                         | 100         | 100                                        | 100         |
| Cost of sales                     | 25                                          | 27          | 26                                         | 27          |
| Gross profit                      | 75                                          | 73          | 74                                         | 73          |
| Operating expenses                |                                             |             |                                            |             |
| Sales and marketing               | 44                                          | 39          | 40                                         | 36          |
| General and administrative        | 15                                          | 11          | 15                                         | 11          |
| Research and development          | 51*                                         | 3           | 20*                                        | 4           |
| Amortization of intangible assets | 2                                           | 2           | 2                                          | 2           |
| Total operating income            | (37)                                        | 18          | (2)                                        | 20          |
| Net income                        | (43)                                        | 61          | (6)                                        | 28          |

\* - Includes \$40.0 million related to the write-off of acquired in-process research and development of Blackstone.

**Three Months Ended September 30, 2006 Compared to Three Months Ended September 30, 2005**

Net sales increased 10% to \$83.4 million for the third quarter of 2006 compared to \$75.8 million for the third quarter of 2005. The impact of foreign currency increased sales by \$0.9 million during the third quarter of 2006 as compared to the third quarter of 2005.

*Sales by Business Segment:*

Net sales in Americas Orthofix (the “Americas”), primarily in the United States, increased to \$41.5 million in the third quarter of 2006 compared to \$36.0 million in the third quarter of 2005, an increase of 15%. The Americas represented 50% of total net sales during the third quarter of 2006 and 47% of total net sales for the third quarter of 2005. While the Americas experienced sales growth in all market sectors, the increase was primarily the result of a 15% increase in sales in the Spine market sector attributable to increased demand for our Spinal-Stim® and Cervical-Stim® products. The Reconstruction and Trauma market sectors were positively affected by increased sales of internal and external fixation products and sales of Physio-Stim®. Non-Orthopedic products increased to \$1.0 million during the third quarter of 2006 compared to \$0.5 million in the third quarter of 2005 due primarily to increased sales of other distributed products.

**Americas Orthofix Sales by Market Sector:**

|                            | <b>Net Sales for the<br/>Three Months Ended September<br/>30,</b> |             |               |  |
|----------------------------|-------------------------------------------------------------------|-------------|---------------|--|
| <b>(In US\$ thousands)</b> | <b>2006</b>                                                       | <b>2005</b> | <b>Growth</b> |  |
| Orthopedic                 |                                                                   |             |               |  |
| Spine                      | \$ 29,263                                                         | \$ 25,422   | 15%           |  |
| Reconstruction             | 2,761                                                             | 1,955       | 41%           |  |
| Trauma                     | 8,531                                                             | 8,092       | 5%            |  |

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|                   |           |           |      |
|-------------------|-----------|-----------|------|
| Total Orthopedic  | 40,555    | 35,469    | 14%  |
| Non-Orthopedic    | 970       | 485       | 100% |
| Americas Orthofix | \$ 41,525 | \$ 35,954 | 15%  |

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Net sales in Americas Breg (“Breg”) increased \$0.7 million to \$18.7 million for the third quarter of 2006 compared to \$18.0 million for the third quarter of 2005, an increase of 4%. The increase in sales was primarily due to the sale of Breg bracing products which increased 7% from the third quarter of 2005. Our new Fusion XT™ knee brace, which experienced positive market response upon its introduction, contributed to this increase. This increase was partially offset by a 13% decrease in sales for pain therapy products resulting in part from delayed introduction of new pain therapy products. All of Breg’s sales are recorded in our Reconstruction market sector.

Net sales in International Orthofix (“International”) increased 6% to \$23.2 million in the third quarter of 2006 compared to \$21.9 million in the third quarter of 2005. International net sales represented 28% and 29% of our total net sales in the third quarter of 2006 and the third quarter of 2005, respectively. International sales in the third quarter of 2006 were positively impacted by a 9% increase in external fixation products which was partially offset by a 13% decrease in sales of the A-V Impulse product. International sales growth in the third quarter was aided by restructuring efforts which included creating business zones and opening a new international distribution center. Sales of Non-Orthopedic products, principally the Laryngeal Mask sold in the United Kingdom and Italy, increased 5% when compared to the same period of the prior year.

**International Orthofix Sales by Market Sector:**

| (In US\$ thousands)    | Net Sales for the<br>Three Months Ended September<br>30, |           |  | Growth |
|------------------------|----------------------------------------------------------|-----------|--|--------|
|                        | 2006                                                     | 2005      |  |        |
| Orthopedic             |                                                          |           |  |        |
| Spine                  | \$ 19                                                    | \$ 26     |  | (27)%  |
| Reconstruction         | 10,737                                                   | 10,062    |  | 7%     |
| Trauma                 | 7,270                                                    | 6,900     |  | 5%     |
| Total Orthopedic       | 18,026                                                   | 16,988    |  | 6%     |
| Non-Orthopedic         | 5,150                                                    | 4,887     |  | 5%     |
| International Orthofix | \$ 23,176                                                | \$ 21,875 |  | 6%     |

*Sales by Market Sector:*

Net sales of spine products increased 15% to \$29.3 million in the third quarter of 2006 compared to \$25.4 million in the third quarter of 2005. As discussed above, the increase is primarily due to sales of our Spinal-Stim and Cervical-Stim products attributable to increased demand in the United States. The Cervical-Stim continues to be the only FDA-approved device for the enhancement of fusion in the cervical spine.

Sales of our reconstruction products increased 7% to \$32.2 million in the third quarter of 2006 compared to \$30.0 million in the third quarter of 2005. The increase of \$2.2 million in this market sector was attributable to sales of the Breg products which increased 7%, sales of internal fixation, including ISKD™ and eight-Plate™, which increased 19% and sales of external fixation products used in reconstruction applications which increased 42%. The majority of these increases were offset by sales of A-V Impulse which decreased 13% as discussed above.

Sales of our trauma products increased 5% to \$15.8 million in the third quarter of 2006, compared to \$15.0 million in the third quarter of 2005. This market sector was positively impacted from a 56% increase in sales of internal fixation products and a 12% increase in sales of Physio-Stim® products due to increased demand.

Sales of our non-orthopedic products grew 14% to \$6.1 million in the third quarter of 2006 compared to \$5.4 million in the third quarter of 2005. The increase was primarily due to an increase in sales of woman's care and other distributed products and an increase in sales of airway management products.

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*Gross Profit* - Our gross profit increased 12.1% to \$62.4 million in the third quarter of 2006, from \$55.6 million in the third quarter of 2005. The increase was primarily due to the increase of 10% in net sales and the increase in sales of higher margin spine stimulation products. Gross profit as a percent of net sales in the third quarter 2006 was 74.8% compared to 73.4% in the third quarter of 2005, which was a result of a favorable product mix resulting from higher sales of higher margin stimulation products.

*Sales and Marketing Expenses* - Sales and marketing expenses, which include commissions, royalties and bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$7.1 million to \$36.3 million in the third quarter of 2006, which includes a charge of \$4.7 million related to the termination of a marketing services agreement with Medtronic Sofamor Danek ("Danek"), compared to \$29.2 million in the third quarter of 2005. The increase in sales and marketing expense was also due to higher commissions on higher sales, increased bad debt expense, an increase in market development expense and share-based compensation cost related to the adoption of SFAS No. 123 (R) of \$0.5 million for which there was no comparable cost in the prior year.

*General and Administrative Expense* - General and administrative expense increased \$3.3 million in the third quarter of 2006 to \$11.7 million compared to \$8.4 million in the third quarter of 2005. This increase is primarily attributable to additional share-based compensation costs related to the adoption of SFAS No. 123 (R) of \$0.7 million for which there was no comparable cost in the prior year, additional corporate development costs of \$0.7 million, additional legal costs of \$0.6 million, and additional market development costs of \$0.2 million.

*Research and Development Expense* - Research and development expense increased \$40.3 million in the third quarter of 2006 to \$42.9 million compared to \$2.6 million in the third quarter of 2005. Research and development expense in the third quarter of 2006 included a charge of \$40.0 million related to the write-off of in-process research and development resulting from the Blackstone acquisition. Share-based compensation costs related to the adoption of SFAS No. 123 (R) was \$0.1 million in the third quarter of 2006 for which there was no comparable cost in the prior year.

*Amortization of Intangible Assets* - Amortization of intangible assets increased \$0.3 million in the third quarter of 2006 to \$1.9 million compared to \$1.6 million in the third quarter of 2005. Amortization expense included \$0.2 million related to amortization of intangibles related to the Blackstone acquisition.

*Interest Income (Expense), net* - Interest expense, net was \$0.5 million in the third quarter of 2006 compared to \$1.2 million of interest expense in the third quarter of 2005. Interest expense for the third quarter of 2006 included interest expense of \$0.7 million related to the senior secured term loan used to finance the Blackstone acquisition. Interest expense in the third quarter of 2005 included the interest related to the term loan associated with the Breg acquisition.

*Other Income (Expense), net* - Other expense, net was \$0.5 million in the third quarter of 2006 compared to other income of \$0.1 million in the third quarter of 2005. The other expense in the third quarter 2006 was due to foreign exchange losses resulting from the strengthening during the quarter of the U.S. Dollar as contrasted to the opposite effect in the third quarter of 2005.

*KCI Settlement, Net of Related Costs* - The gain, net of related costs, on the settlement of the KCI litigation in the third quarter of 2005 was \$40.9 million for which there was no comparable gain in the third quarter of 2006.

*Income Tax Expense* - Our estimated worldwide effective tax rate was 12.6% and 14.1% during the third quarter of 2006 and 2005, respectively. The effective tax rate for the third quarter of 2006 reflects the non-deductibility, for tax purposes, of the \$40.0 million purchased in-process research and development charge associated with the Blackstone acquisition. Excluding the charge for in-process research and development, our effective tax rate was 46%. During the third quarter of 2006, we incurred tax expense of \$0.3 million related to our European restructuring and tax

adjustments in foreign jurisdictions of \$0.4 million. The effective tax rate for the third quarter of 2006 was also affected by a higher percentage of income being earned in the United States, a higher tax jurisdiction. The effective tax rate for the third quarter of 2005 was affected by the gain recorded from the KCI settlement which was recorded at Novamedix Distribution Limited, a wholly-owned Cypriot subsidiary, which is in a favorable tax jurisdiction.

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**Net Income (Loss)** - Net loss for the third quarter of 2006 was \$35.4 million, or \$2.19 per basic share and \$2.17 per diluted share, compared to net income of \$46.0 million, or \$2.88 per basic share and \$2.81 per diluted share, for the third quarter of 2005. The weighted average number of basic common shares outstanding was 16,193,086 and 15,986,599 during the third quarter of 2006 and 2005, respectively. The weighted average number of diluted common shares outstanding was 16,322,827 and 16,384,106 during the third quarter of 2006 and 2005, respectively.

**Nine Months Ended September 30, 2006 Compared to Nine Months Ended September 30, 2005***Sales by Business Segment:*

Net sales increased 7% to \$249.2 million for the first nine months of 2006 compared to \$233.0 million for the first nine months of 2005. The impact of foreign currency decreased sales by \$0.9 million during the first nine months of 2006 as compared to the first nine months of 2005.

Net sales in the Americas, primarily in the United States, increased \$16.7 million to \$122.3 million in the first nine months of 2006 compared to \$105.6 million in the first nine months of 2005, an increase of 16%. The Americas represented 49% of total net sales during the first nine months of 2006 and 45% of total net sales for the first nine months of 2005. The increase in sales was primarily the result of an 18% increase in sales in the Spine market sector which was attributable to increased demand for our Spinal-Stim® and Cervical-Stim® products. The Reconstruction market sector also experienced a 31% increase in sales which was attributable to growth in sales of newer internal reconstruction products such as the eight-Plate™ and ISKD. In the Americas Trauma market sector, external fixation devices are sharing the market for treatment of difficult fractures with alternatives such as plating and nailing. Recognizing this trend, we have introduced the Contours VPS for distal radius fractures, the PC.C.P. for hip fractures, and on a limited release the CentroNail™. Growth from these products together with growth from the Physio-Stim for long-bone non-unions enabled us to offset a negative 1% growth for external fixation and show an overall 2% growth in Trauma for the first nine months of 2006 compared to 2005. Sales of non-orthopedic products increased \$1.2 million due primarily to an increase in sales of other distributed products.

**Americas Orthofix Sales by Market Sector:**

| (In US\$ thousands) | Net Sales for the<br>Nine Months Ended September<br>30, |            |  | Growth |
|---------------------|---------------------------------------------------------|------------|--|--------|
|                     | 2006                                                    | 2005       |  |        |
| Orthopedic          |                                                         |            |  |        |
| Spine               | \$ 86,722                                               | \$ 73,752  |  | 18%    |
| Reconstruction      | 8,235                                                   | 6,270      |  | 31%    |
| Trauma              | 24,908                                                  | 24,345     |  | 2%     |
| Total Orthopedic    | 119,865                                                 | 104,367    |  | 15%    |
| Non-Orthopedic      | 2,420                                                   | 1,229      |  | 97%    |
| Americas Orthofix   | \$ 122,285                                              | \$ 105,596 |  | 16%    |

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Net sales in Breg increased 5% to \$55.9 million for the first nine months of 2006 compared to \$53.4 million for the first nine months of 2005. The increase in sales was primarily due to the sale of Breg bracing products which increased 10% from the first nine months of 2005. Our new Fusion™ XT knee brace was the primary contributor to the increase. This increase was partially offset by a 11% decrease in sales for pain therapy products resulting from delayed introduction of new pain therapy products. All of Breg's sales are recorded in our Reconstruction market sector. Breg net sales represented 22% and 23% of our total net sales in the nine months of 2006 and 2005, respectively.

Net sales in International decreased 4% to \$71.0 million in the first nine months of 2006 compared to \$74.1 million in first nine months of 2005. International net sales represented 29% and 32% of our total net sales in the first nine months of 2006 and 2005, respectively. The impact of foreign currency decreased International sales by 1.8%, or \$1.3 million, during the first nine months of 2006 as compared to the first nine months of 2005. International sales in the first nine months of 2006 were also negatively impacted by a 17% decrease in sales of the A-V Impulse product. International sales were also negatively impacted in the Reconstruction and Trauma market sectors by a continued shift towards internal fixation from external fixation products. In recognizing this market preference, we have added new internal fixation products to our product offering, which have increased 40% in the first nine months as compared to the first nine months of 2005. Sales of Non-Orthopedic products, principally the Laryngeal Mask sold in the United Kingdom and Italy, were down 3% when compared to the same period of the prior year.

**International Orthofix Sales by Market Sector:**

| (In US\$ thousands)    | Net Sales for the<br>Nine Months Ended September<br>30, |           |        |
|------------------------|---------------------------------------------------------|-----------|--------|
|                        | 2006                                                    | 2005      | Growth |
| Orthopedic             |                                                         |           |        |
| Spine                  | \$ 59                                                   | \$ 95     | (38)%  |
| Reconstruction         | 32,782                                                  | 34,737    | (6)%   |
| Trauma                 | 22,613                                                  | 23,230    | (3)%   |
| Total Orthopedic       | 55,454                                                  | 58,062    | (4)%   |
| Non-Orthopedic         | 15,579                                                  | 16,014    | (3)%   |
| International Orthofix | \$ 71,033                                               | \$ 74,076 | (4)%   |

*Sales by Market Sector:*

Net sales of spine products increased 18% to \$86.8 million in the first nine months of 2006 compared to \$73.8 million in the first nine months of 2005. As discussed above, the increase is primarily due to sales of our Spinal-Stim and Cervical-Stim products attributable to increased demand in the United States.

Sales of our reconstruction products increased 3% to \$96.9 million in the first nine months of 2006 compared to \$94.3 million in the first nine months of 2005. The increase in this market sector was attributable to increased sales of the Breg products which increased 7% worldwide together with increased sales of internal fixation products. The majority of this growth was offset by decreased sales of our A-V Impulse products as discussed above and decreased sales in other reconstruction products due to the discontinuation of certain distributed products in the International market.

Sales of our trauma products were nearly flat at \$47.5 million in the first nine months of 2006, compared to \$47.6 million in the first nine months of 2005. This market sector was negatively impacted from a 7% decline in sales of external fixation products which was due to fluctuations of foreign currency and decreased demand for external

fixation products partially offset by increased demand for internal fixation and Physio-Stim products.

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Sales of our non-orthopedic products increased 4% to \$18.0 million in the first nine months of 2006, compared to the first nine months of 2005. Sales of woman's care and other distributed products increased; however, this increase was offset by a decrease in sales of airway management products.

*Gross Profit* - Our gross profit increased 8% to \$185.6 million in the first nine months of 2006, from \$171.2 million in the first nine months of 2005. The increase was primarily due to the increase of 7% in net sales. Gross profit as a percent of net sales in the first nine months of 2006 was 74.5% compared to 73.5% in the first nine months of 2005. The higher gross profit margin was a result of a favorable product mix, resulting from the sales of higher margin stimulation products as well as ongoing operational improvement initiatives. Share-based compensation costs related to the adoption of SFAS No. 123(R) in the first nine months of 2006 was \$0.2 million for which there was no comparable cost in the prior year.

*Sales and Marketing Expenses* - Sales and marketing expenses, which include commissions, royalties and bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$13.4 million to \$99.0 million in the first nine months of 2006 which includes a charge of \$4.7 million related to the termination of a marketing services agreement with Danek, compared to \$85.4 million in the first nine months of 2005. Sales and marketing expense as a percent of net sales increased to 39.7% in the first nine months of 2006 from 36.7% in the first nine months of 2005. The increase in sales and marketing expense is primarily due to higher commissions on higher sales, increased bad debt expense, an increase in ongoing market development expenses, and share-based compensation costs related to the adoption of SFAS No. 123(R). Share-based compensation costs related to the adoption of SFAS No. 123(R) in the first nine months of 2006 was \$0.9 million for which there was no comparable cost in the prior year.

*General and Administrative Expense* - General and administrative expense increased \$10.5 million in the first nine months of 2006 to \$36.3 million compared to \$25.7 million in the first nine months of 2005. This increase is primarily attributable to management transition costs of \$1.7 million, which included \$0.7 million of non-cash share-based compensation, additional share-based compensation related to the adoption of SFAS No. 123(R) of \$3.6 million for which there is no comparable cost in the prior year, additional corporate development costs of \$1.0 million, additional legal costs of \$0.8 million, and market development activities of \$0.4 million.

*Research and Development Expense* - Research and development expense increased \$39.9 million in the first nine months of 2006 to \$48.6 million compared to \$8.7 million in the first nine months of 2005. Research and development expense in the first nine months of 2006 included a charge of \$40.0 million related to the write-off of in-process research and development resulting from the Blackstone acquisition. Share-based compensation costs related to the adoption of SFAS No. 123(R) in the first nine months of 2006 was \$0.2 million for which there was no comparable cost in the prior year.

*Amortization of Intangible Assets* - Amortization of intangible assets was \$5.4 million in the first nine months of 2006 compared to \$4.9 million for the first nine months of 2005. Amortization expense included \$0.2 million related to amortization of intangibles related to the Blackstone acquisition.

*Interest Income (Expense), net* - Interest income, net was \$0.2 million in the first nine months of 2006 compared to an expense of \$3.7 million in the first nine months of 2005. The reduction in interest expense in the first nine months of 2006 when compared to the same period in 2005 is the result of the repayment of our senior secured term loan associated with the Breg acquisition.

*Other Income (Expense), net* - Other expense, net was \$0.8 million in the first nine months of 2006 as a result of foreign currency losses compared to other income of \$1.5 million in the first nine months of 2005 which was primarily attributable to \$2.4 million of deferred royalty income resulting from the conclusion of the BoneSource

agreement with Stryker which was partially offset by \$0.9 million of foreign currency losses.

*KCI Settlement, Net of Related Costs* - In the first nine months of 2006, we entered into final agreements with certain former owners of Novamedix, which established the portion of the proceeds we were required to disburse in connection with the KCI settlement. Accordingly, we recorded a gain of \$1.1 million which was the difference between what we had reserved to disburse at December 31, 2005 and the amount of the final settlement obligations. This gain compares to \$40.4 million of gain in the first nine months of 2005 which relates to the settlement of the KCI litigation.

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*Income Tax Expense* - Our estimated worldwide effective tax rate was (348.3%) and 21.8% during the first nine months of 2006 and 2005, respectively. The effective tax rate for the first nine months of 2006 reflects the non-deductibility, for tax purposes, of the \$40.0 million purchased in-process research and development charge associated with the Blackstone acquisition. Excluding the charge for in-process research and development, our effective tax rate is 31%. Our nine month 2006 effective tax rate benefited from a one-time tax benefit of \$2.9 million resulting from our election to adopt a new tax provision in Italy. The election allowed us to increase, for tax purposes only, the value of our trademarks in Italy by approximately \$15.0 million. We incurred a tax liability of \$2.7 million from applying a 19% tax rate to the revaluation of the trademark value. We will receive a future tax benefit of \$5.6 million associated with amortization of that step-up in value which is based on the current Italian tax rates of approximately 37%. The net of the \$5.6 million deferred tax asset and the \$2.7 million tax liability resulted in a \$2.9 million non-recurring discrete tax benefit. Without this discrete item, our estimated worldwide effective tax rate for the nine months ended September 30, 2006 was 38% as a result of a higher proportion of pre-tax income being earned in the United States, a higher tax jurisdiction, in 2006 when compared to the same period of the prior year excluding the impact of the KCI settlement (as discussed below). The effective tax rate for the first nine months of 2005 was affected by the gain recorded from the KCI settlement which was recorded at Novamedix Distribution Limited, a wholly-owned Cypriot subsidiary, which is in a favorable tax jurisdiction. This lower rate was slightly offset by a change in tax law in the United Kingdom and earning more taxable income in higher tax jurisdictions such as the United States.

*Net Income (Loss)* - Net loss for the first nine months of 2006 was \$14.4 million, or \$0.90 per basic share and \$0.89 per diluted share, compared to \$66.2 million, or \$4.17 per basic share and \$4.07 per diluted share, for the first nine months of 2005. The weighted average number of basic common shares outstanding was 16,084,388 and 15,881,902 during the first nine months of 2006 and 2005, respectively. The weighted average number of diluted common shares outstanding was 16,229,221 and 16,279,724 during the first nine months of 2006 and 2005, respectively.

## **Liquidity and Capital Resources**

Cash and cash equivalents at September 30, 2006 were \$56.6 million of which \$19.5 million is subject to certain restrictions under the senior secured credit agreement described below. This compares to \$77.5 million at December 31, 2005 of which \$13.8 million was subject to certain restrictions under a previous senior secured credit agreement, which was fully repaid and cancelled as of March 31, 2006.

Net cash used in operating activities was \$9.4 million for the first nine months of 2006 compared to \$94.8 million, including \$67.5 million from the KCI settlement, provided by operating activities in the first nine months of 2005. Net cash (used in) provided by operating activities is comprised of net income (loss), non-cash items (including share-based compensation and non-cash purchase accounting items from the Blackstone acquisition, notably in-process research and development) and changes in working capital. Net income decreased \$80.6 million to a loss of \$14.4 million in the first nine months of 2006 from \$66.2 million in the comparable 2005 period. The reduction in net income includes \$40.0 million of in-process research and development from the Blackstone transaction and the non-recurring of \$37.4 million in after tax income from the KCI settlement in 2005. Non-cash items increased \$39.1 million in the first nine months of 2006 compared to the same period in 2005 principally as a result of the non-cash effect of share based compensation and the recording of Blackstone in-process research and development. Working capital accounts consumed \$48.0 million of cash in the first nine months of 2006, including a reduction in other current liabilities related principally to the KCI settlement. Excluding the effect of the KCI settlement, working capital consumed \$8.9 million of cash in the first nine months of 2006 compared to \$24.4 million in the same period in 2005. The principal uses of cash for working capital were for increases in accounts receivable and inventory to support additional sales and certain operational initiatives. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 95 days at September 30, 2006 compared to 98 days at September 30, 2005 and inventory turns of 2.0 times at September 30, 2006 compared to 2.3

times at September 30, 2005. The lower inventory turns and resultant higher inventory reflect inventory investment to open an international distribution center, the purchase of a safety stock of A-V Impulse Impads to support the transfer of production from the UK to Mexico and inventories associated with new internal fixation product lines.

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Net cash used in investing activities was \$343.6 million during the first nine months of 2006 compared to \$8.9 million during the first nine months of 2005. On September 22, 2006 we purchased Blackstone for \$333.0 million plus various transaction costs. In addition, during the first nine months of 2006, we invested \$6.8 million in capital expenditures and we paid \$1.1 million to purchase 52% of our distributor of Breg products in Germany. During the first nine months of 2005, we invested \$8.9 million in capital expenditures.

Net cash provided from financing activities was \$325.5 million in the first nine months of 2006 compared to \$17.7 million used by financing activities during the first nine months of 2005. In March 2006, we repaid the remaining \$14.8 million of principal of the senior secured term loan, which was obtained to finance the Breg acquisition. On September 22, 2006, we borrowed \$330.0 million in the form of a new senior secured credit agreement, which along with cash balances were used to finance the acquisition of Blackstone and pay debt issuance and other costs. In addition, we received proceeds of \$11.2 million from the issuance of 376,376 shares of our common stock upon the exercise of stock options and shares issued pursuant to our employee stock purchase plan and \$2.0 million of related tax benefit. In the first nine months of 2005 we prepaid \$24.0 million of principal of the Breg senior secured term loan and we received proceeds of \$6.4 million from the issuance of 292,606 shares of our common stock upon the exercise of stock options and shares issued pursuant to our employee stock purchase plan.

On September 22, 2006 our wholly-owned US holding company subsidiary, Orthofix Holdings, Inc. (“Orthofix Holdings”), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million, the proceeds of which, together with cash balances were used for payment of the purchase price of Blackstone; and (2) a six-year revolving credit facility of \$45.0 million. As of September 30, 2006 and as of November 6, 2006 we had no amounts outstanding under the revolving credit facility and \$330.0 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of LIBOR or prime rate plus a margin, currently LIBOR plus 1.75%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. Our effective interest rate as of September 30, 2006 on our senior secured debt is 7.12%. The Company, certain foreign subsidiaries of the Company, including Colgate Medical Limited (Orthofix Holdings’s immediate parent) and certain of Orthofix Holdings’s direct and indirect subsidiaries, including Orthofix Inc., Breg and Blackstone, have guaranteed the obligations of Orthofix Holdings under the senior secured credit facility. The obligations of Orthofix Holdings under the senior secured bank facility and the guarantors under their guarantees are secured by the pledge of their respective assets located in the United States.

At September 30, 2006, we had outstanding borrowings of 2.5 million Euro (\$3.1 million) and unused available lines of credit of approximately 4.1 million Euro (\$5.1 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 will continue to search for viable acquisition candidates that would expand our global presence as well as add additional products appropriate for current distribution channels. An acquisition of another company or product line by us could result in our incurrence of additional debt and contingent liabilities.

We believe that current cash balances together with projected cash flows from operating activities, the available Italian line of credit, the exercise of stock options, and our debt capacity are sufficient to cover anticipated working capital and capital expenditure needs including research and development costs over the near term.

Table of Contents*Contractual Obligations*

The following chart sets forth changes to our contractual obligations that have occurred since December 31, 2005:

| <b>Contractual Obligations</b><br><b>(In thousands)</b> | <b>Payments Due By Period</b> |                             |                     |                     |                         |
|---------------------------------------------------------|-------------------------------|-----------------------------|---------------------|---------------------|-------------------------|
|                                                         | <b>Total</b>                  | <b>Less Than 1<br/>Year</b> | <b>1 to 3 Years</b> | <b>4 to 5 Years</b> | <b>Over 5<br/>Years</b> |
| Senior secured term loan:                               |                               |                             |                     |                     |                         |
| As of December 31, 2005                                 | \$ 14,750                     | \$ 14,750                   | \$ -                | \$ -                | \$ -                    |
| As of September 30, 2006                                | \$ 330,000                    | \$ 3,300                    | \$ 6,600            | \$ 6,600            | \$ 313,500              |
| Other borrowings:                                       |                               |                             |                     |                     |                         |
| As of December 31, 2005                                 | \$ 458                        | \$ 437                      | \$ 21               | \$ -                | \$ -                    |
| As of September 30, 2006                                | \$ 3,278                      | \$ 3,240                    | \$ 38               | \$ -                | \$ -                    |

The senior secured term loan balance as of December 31, 2005 was fully repaid prior to June 30, 2006. On September 22, 2006, a new credit agreement was entered into by Orthofix Holdings, Inc. with Orthofix International N.V., certain domestic and foreign direct and indirect subsidiaries concurrent with the closing of the Blackstone acquisition. This credit agreement includes a seven year, \$330.0 million term loan.

In addition to scheduled contractual obligations of the debt as set forth above, our credit agreement requires us to make mandatory prepayments with (a) the excess cash flow (as defined in the credit agreement) of Orthofix International N.V. and its subsidiaries, in an amount equal to 50% of the excess annual cash flow beginning with the year ending December 31, 2007, provided, however, if the leverage ratio (as defined in the credit agreement) is less than or equal to 1.75 to 1.00, there will be no mandatory excess cash flow prepayments, (b) 100% of the net cash proceeds of any debt issuances by Orthofix International N.V. or any of its subsidiaries or 50% of the net cash proceeds of equity issuances by any such party, excluding the exercise of stock options, provided, however, if the leverage ratio is less than or equal to 1.75 to 1.00 at the end of the preceding fiscal year, Orthofix Holdings shall not be required to prepay the loans with the proceeds of any such debt or equity issuances, (c) the net cash proceeds of asset dispositions over a minimum threshold, or (d) unless reinvested, insurance proceeds or condemnation awards.

**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 goods, and costs of operations, 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 September 30, 2006, we had a currency hedge transaction in place to balance our Euro-denominated current liabilities with our Euro-denominated current assets. See Item 2 - "Management's Discussion and Analysis of Financial Condition and Results of Operations".

We are exposed to interest rate risk in connection with our senior secured term loan and borrowings under our revolving credit facility, which bear interest at floating rates based on London Inter-Bank Offered Rate (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.



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As of September 30, 2006, Orthofix Holdings had \$330.0 million of variable rate term debt represented by borrowings under its senior secured term loan at a floating interest rate of LIBOR or prime rate plus a margin, currently LIBOR plus 1.75%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. The effective interest rate as of September 30, 2006 on the senior secured debt is 7.12%. Based on the balance outstanding under the credit facility as of December 31, 2006 an immediate change of one percentage point in the applicable interest rate on the variable rate debt would cause an increase or decrease in interest expense of approximately \$3.3 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 face 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 face transactional currency exposures when foreign subsidiaries (or the Company itself) enter into transactions, generally on an intercompany basis, denominated in currencies other than their functional currency. As of September 30, 2006, we had an uncovered intercompany receivable denominated in Euro for approximately 48.2 million. We are currently evaluating our options to limit the foreign currency exposure on this receivable.

**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 our disclosure controls and procedures (as defined in Exchange Act Rule 13a - 15(e) or 15d - 15(e)) as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

Other than as set forth below with respect to our recent acquisition of Blackstone, there has been no change to our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We completed the acquisition of Blackstone in September 2006, as more fully described in Note 7 to the unaudited condensed consolidated financial statements included in Part 1, Item 1, herein. As part of our ongoing integration activities, we are in the process of incorporating our controls and procedures into Blackstone. Management has excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of September 30, 2006 certain elements of the internal control over financial reporting of Blackstone.

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**PART II**

**OTHER INFORMATION**

**Item 1. Legal Proceedings**

The Company's subsidiary, Blackstone Medical, is a defendant in a patent infringement lawsuit captioned *Medtronic Sofamor Danek USA Inc., Warsaw Orthopedic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Sofamor Danek Deggendorf, GmbH v. Blackstone Medical, Inc.*, Civil Action No. 06-30165-MAP, filed on September 22, 2006 in the United States District Court for the District of Massachusetts. The plaintiffs allege that (i) they are the exclusive licensees of United States Patent Nos. 6,926,718 B1, 6,936,050 B2, and (ii) Blackstone Medical's making, selling, offering for sale, and using within the United States its Anterior Cervical Plate and 3° Anterior Cervical Plate products is infringing and has infringed the Patents, and that such infringement has been willful. The Complaint requests both damages and an injunction against Blackstone Medical's further alleged infringement of the Patents. The Complaint does not specifically state an amount of damages. On October 18, 2006, Blackstone Medical filed its Answer and Counterclaims, denying infringement and asserting that the Patents are invalid.

**Item 1A. Risk Factors**

Other than as set forth below 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 year ended December 31, 2005.

**Third parties may claim that we infringe on their proprietary rights and may prevent us from manufacturing and selling certain of our products.**

There has been substantial litigation in the orthopedic medical devices industry with respect to the manufacture, use and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to defend against allegations relating to the infringement of patent or proprietary rights of third parties. Any such litigation could, among other things:

- require us to incur substantial expense, even if the costs of our defense are covered by insurance or we are successful in the litigation;
- require us to divert significant time and effort of our technical and management personnel;
- result in the loss of our rights to develop or make certain products; and
- require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties or to satisfy judgments or to settle actual or threatened litigation.

Although patent and intellectual property disputes within the orthopedic medical devices industry have often been settled through assignments, licensing or similar arrangements, costs associated with these arrangements may be substantial and could include the long-term payment of royalties. Furthermore, the required assignments or licenses may not be made available to us on acceptable terms. Accordingly, an adverse determination in a judicial or administrative proceeding or a failure to obtain necessary assignments or licenses could prevent us from manufacturing and selling some products or increase our costs to market these products.

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For example, the Company's subsidiary, Blackstone, maintains a license agreement with Cross Medical, Inc./EBI ("Cross/EBI") covering certain pedicle screw products currently sold by Blackstone. Prior to the completion of its acquisition by the Company, Blackstone requested that Cross/EBI consent to the assignment of the license agreement to the extent Blackstone's acquisition by the Company constituted an assignment thereunder. At this time, Cross/EBI and the Company are negotiating the terms of such consent. Although the Company believes that no consent is necessary for Blackstone to maintain its rights under the license agreement, and that to the extent such a consent is necessary, Cross/EBI is required to provide it under the terms of the agreement, there can be no assurance that Cross/EBI will not challenge Blackstone's rights under the license agreement if current negotiations are not successful.

**In order to compete, we must attract, retain and motivate key employees, and our failure to do so could have an adverse effect on our results of operations.**

In order to compete, we must attract, retain and motivate executives and other key employees, including those in managerial, technical, sales, marketing and support positions. Hiring and retaining qualified executives, engineers, technical staff and sales representatives are critical to our business, and competition for experienced employees in the medical device industry can be intense. To attract, retain and motivate qualified employees, we utilize stock-based incentive awards such as employee stock options. If the value of such stock awards does not appreciate as measured by the performance of the price of our common stock and ceases to be viewed as a valuable benefit, our ability to attract, retain and motivate our employees could be adversely impacted, which could negatively affect our results of operations and/or require us to increase the amount we expend on cash and other forms of compensation. In addition, our adoption of Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share-Based Payment," during our first quarter of 2006 will result in significant additional compensation expense compared to prior periods.

**Our results of operations could vary as a result of the methods, estimates and judgments we use in applying our accounting policies.**

The methods, estimates and judgments we use in applying our accounting policies have a significant impact on our results of operations (see "Critical Accounting Estimates" in Part II, Item 7 of our Annual Report filed on Form 10-K). Such methods, estimates and judgments are, by their nature, subject to substantial risks, uncertainties and assumptions, and factors may arise over time that leads us to change our methods, estimates and judgments. Changes in those methods, estimates and judgments could significantly affect our results of operations. In particular, beginning in our first quarter of 2006, the calculation of share-based compensation expense under SFAS No. 123(R) will require us to use valuation methodologies (which were not developed for use in valuing employee stock options) and a number of assumptions, estimates and conclusions regarding matters such as expected forfeitures, expected volatility of our share price, the expected dividend rate with respect to our common stock and the exercise behavior of our employees. Furthermore, there are no means, under applicable accounting principles, to compare and adjust our expense if and when we learn of additional information that may affect the estimates that we previously made, with the exception of changes in expected forfeitures of share-based awards. Factors may arise over time that leads us to change our estimates and assumptions with respect to future share-based compensation arrangements, resulting in variability in our share-based compensation expense over time. Changes in forecasted share-based compensation expense could impact our gross margin percentage; research and development expenses; sales and marketing expenses; general and administrative expenses; and our tax rate.

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**Our acquisition of Blackstone Medical could present challenges for us.**

On September 22, 2006, we completed the acquisition of Blackstone Medical. We are in the process of integrating the operations of Blackstone Medical into our business. We may not be able to successfully integrate Blackstone Medical's operations into our business and achieve the anticipated benefits of the acquisition. The integration of Blackstone Medical's operations into our business involves numerous risks, including:

- difficulties in incorporating Blackstone Medical's product lines, sales personnel and marketing operations into our business;
- the diversion of our resources and our management's attention from other business concerns;
- the loss of any key distributors;
- the loss of any key employees; and
- the assumption of unknown liabilities.

In addition, Blackstone Medical's business is subject to many of the same risks and uncertainties that apply to our other business operations, such as risks relating to the protection of Blackstone Medical's intellectual property and proprietary rights, including patents that it owns or licenses. If Blackstone Medical's intellectual property and proprietary rights are challenged, or if third parties claim that Blackstone Medical infringes on their proprietary rights, our business could be adversely affected.

Failure to overcome these risks or any other problems encountered in connection with the acquisition of Blackstone Medical could adversely affect our business, prospects and financial condition. In addition, if Blackstone Medical's operations and financial results do not meet our expectations, we may not realize synergies, operating efficiencies, market position, or revenue growth we anticipate from the acquisition.

**We may be subject to extensive government regulation that increases our costs and could limit our ability to market or sell our products.**

The medical devices we manufacture and market are subject to rigorous regulation by the Food and Drug Administration, or FDA, and numerous other federal, state and foreign governmental authorities. These authorities regulate the development, approval, classification, testing, manufacture, labeling, marketing and sale and recall of medical devices. For a description of these regulations, see Item 1 - "Business - Government Regulation" in our Annual Report on Form 10-K for the year ended December 31, 2005.

The approval by governmental authorities, including the FDA in the United States, is generally required before any medical devices may be marketed in the United States or other countries. We cannot predict whether in the future, the U.S. or foreign governments may impose regulations that have a material adverse effect on our business, financial condition or results of operations. The process of obtaining FDA and other regulatory approvals to develop and market a medical device can be costly and time-consuming, and is subject to the risk that such approvals will not be granted on a timely basis if at all. The regulatory process may delay or prohibit the marketing of new products and impose substantial additional costs if the FDA lengthens review times for new devices.

The FDA has the ability to change the regulatory classification of an approved device from a higher to a lower regulatory classification which could materially adversely impact our ability to market or sell our devices. Our subsidiary, Orthofix, Inc. is currently involved in a proceeding before the FDA addressing whether the FDA classification of our Physio-Stim and Spinal-Stim bone growth stimulation products should be reclassified from FDA Class III to FDA Class II. We are actively participating in this proceeding and maintain that the current FDA Class III classification is correct. A meeting was held on June 2, 2006 before the FDA's Orthopedic and Rehabilitation Devices panel for the purpose of gathering information to allow the panel to recommend to the FDA whether reclassification is

appropriate. At the conclusion of the meeting, the Panel determined that the present FDA Class III classification for the products at issue is proper. We do not know when or whether the FDA will reach a determination on this classification issue or whether any such determination would adversely impact our ability to market or sell these products.

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**We face risks related to foreign currency exchange rates.**

Because some of our revenue, operating expenses, assets and liabilities are denominated in foreign currencies, we are subject to foreign exchange risks that could adversely affect our operations and reported results. To the extent that we incur expenses or earn revenue in currencies other than the U.S. dollar, any change in the values of those foreign currencies relative to the U.S. dollar could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our current assets denominated in foreign currency are greater or less than our current liabilities denominated in foreign currencies, we have potential foreign exchange exposure. As part of our European restructuring in third quarter 2006, as of September 30, 2006, we had a Euro denominated receivable of 48.3 million for which there was no related Dollar denominated payable. We are exposed to potential movements in currency rates between the Euro and the Dollar. We are currently evaluating our options to limit the currency exposure on this Euro denominated receivable.

We have substantial activities outside of the United States that are subject to the impact of foreign exchange rates. The fluctuations of foreign exchange rates during 2006 have had a negative impact of \$0.9 million on net sales outside of the United States. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we enter into currency hedges from time to time. At September 30, 2006, we had outstanding a foreign currency hedge for 5.0 million Euros to balance our current liabilities denominated in Euros with our current assets denominated in Euros.

**Our subsidiary Orthofix Holdings, Inc.'s senior secured bank credit facility contains significant financial and operating restrictions and mandatory prepayments that may have an adverse effect on our operations and limit our ability to grow our business.**

When we acquired Blackstone on September 22, 2006, one of our wholly-owned subsidiaries, Orthofix Holdings, Inc. (Orthofix Holdings), entered into a senior secured bank credit facility with a syndicate of financial institutions to finance the transaction. Orthofix and certain of Orthofix Holdings's direct and indirect subsidiaries, including Orthofix Inc., Breg, and Blackstone have guaranteed the obligations of Orthofix Holdings under the senior secured bank facility. The senior secured bank 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 upon which we had not drawn as of November 6, 2006.

Further, in addition to scheduled debt payments, the credit agreement requires us to make mandatory prepayments with (a) the excess cash flow (as defined in the credit agreement) of Orthofix and its subsidiaries, in an amount equal to 50% of the excess annual cash flow beginning with the year ending December 31, 2007, provided, however, if the leverage ratio (as defined in the credit agreement) is less than or equal to 1.75 to 1.00, there will be no mandatory excess cash flow prepayments, (b) 100% of the net cash proceeds of any debt issuances by Orthofix or any of its subsidiaries or 50% of the net cash proceeds of equity issuances by any such party, excluding the exercise of stock options, provided, however, if the leverage ratio is less than or equal to 1.75 to 1.00 at the end of the preceding fiscal year, Orthofix Holdings shall not be required to prepay the loans with the proceeds of any such debt or equity issuance, (c) the net cash proceeds of asset dispositions over a minimum threshold, or (d) unless reinvested, insurance proceeds or condemnation awards. These mandatory prepayments could limit our ability to reinvest in our business.

The credit agreement contains negative covenants applicable to Orthofix and its subsidiaries, including restrictions on indebtedness, liens, dividends and mergers and sales of assets. The credit agreement also contains certain financial covenants, including a fixed charge coverage ratio and a leverage ratio applicable to 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. See Part I, Item 2 - "Management's Discussion and Analysis of Financial Condition and Results of Operations" - "Liquidity and Capital Resources" of this Form 10-Q.



Table of Contents**Item 6. Exhibits**

|                   | (a)                                                                                                                                                                                                                                                                                            | <b><u>Exhibits</u></b> |
|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Exhibit<br>Number | Description                                                                                                                                                                                                                                                                                    |                        |
| 3.1               | Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).                                                                                                                        |                        |
| 3.2               | Articles of Association of the Company as Amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2004 and incorporated herein by reference).                                                                                          |                        |
| 10.1              | Orthofix Inc. Employee Stock Purchase Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).                                                                                                 |                        |
| 10.2              | Orthofix International N.V. Staff Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).                                                                                        |                        |
| 10.3              | Form of Performance Accelerated Stock Option under the Staff Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).                                                             |                        |
| 10.4              | Form of Performance Accelerated Stock Option Inducement Agreement (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2003 and incorporated here in by reference).                                                                         |                        |
| 10.5              | Orthofix International N.V. 2004 Long Term Incentive Plan, as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2004 and incorporated herein by reference).                                                                      |                        |
| 10.6              | Form of Nonqualified Stock Option Agreement Under the Orthofix International N.V. 2004 Long Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed April 17, 2006 and incorporated herein by reference)                                                    |                        |
| 10.7              | Form of Nonqualified Stock Option Agreement for Non-Employee Directors under the Orthofix International N.V. 2004 Long Term Incentive Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2004 and incorporated herein by reference). |                        |
| 10.8              | Employment Agreement, dated as of April 15, 2005, between Orthofix International N.V. 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).                                                     |                        |
| 10.9              | Employment Agreement, dated as of July 13, 2006, between the Company and Thomas Hein (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and                                                                                                                  |                        |

incorporated herein by reference).

- 10.10 Employment Agreement, dated as of November 20, 2003, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2003 and incorporated herein by reference).

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|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.11 | Full Recourse Promissory Note between Orthofix International N.V. and Charles W. Federico dated January 10, 2002 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).                                                                                                                                                                                                                                                                                      |
| 10.12 | Full Recourse Promissory Note between Orthofix International N.V. and Gary D. Henley dated January 10, 2002 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).                                                                                                                                                                                                                                                                                           |
| 10.13 | 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).                                                                                                                                                                                                                                          |
| 10.14 | Voting and Subscription Agreement dated as of November 20, 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 January 8, 2004 and incorporated herein by reference).                                                                                                                                                                                                                                 |
| 10.15 | Employee Agreement, as amended, dated December 29, 2005 between Orthofix International N.V. 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).                                                                                                                                                                                                                                                                                                       |
| 10.16 | 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, 2005 and incorporated herein by reference).                                                                                                                                                                                                                                                                                                                                                                           |
| 10.17 | Settlement Agreement, dated February 23, 2006, between Intavent Orthofix Limited, a wholly-owned subsidiary of Orthofix International N.V. and Galvin Mould (filed as an exhibit to the Company's current report on Form 8-K filed on April 17, 2006 and incorporated herein by reference).                                                                                                                                                                                                                                                               |
| 10.18 | Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference).                                                                                                                                                                                                                                                                                                                                        |
| 10.19 | Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference).                                                                                                                                                                                                                                                                                                                                         |
| 10.20 | Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference).                                                                                                                                                                                                                                                                                                                                       |
| 10.21 | Credit Agreement, dated as of September 22, 2006, among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, the several banks and other financial institutions as may from time to time become parties thereunder, and Wachovia Bank, National Association (filed as an exhibit to the Company's current report on Form 8-K filed September 27, 2006 and incorporated herein by reference). |

10.22 Agreement and Plan of Merger, dated as of August 4, 2006, among Orthofix International N.V., Orthofix Holdings, Inc., New Era Medical Corp., Blackstone Medical, Inc., the principal shareholders of Blackstone Medical, Inc. and William G. Lyons, III, as the Equityholders' Representative (filed as an exhibit to the Company's Amendment No. 1 to current report on Form 8-K filed August 7, 2006 and incorporated herein by reference).

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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.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORTHOFIX INTERNATIONAL N.V.

Date: November 9, 2006

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

Date: November 9, 2006

By: /s/ Thomas Hein  
Name: Thomas Hein  
Title: Chief Financial Officer