

ORTHOFIX INTERNATIONAL N V  
Form 10-Q  
August 08, 2008

---

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2008

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

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

As of August 7, 2008, 17,099,458 shares of common stock were issued and outstanding.

---

---

---

## Table of Contents

PART I FINANCIAL INFORMATION		3
Item 1.	<u>Condensed Consolidated Financial Statements</u>	3
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	33
Item 4.	<u>Controls and Procedures</u>	34
PART II OTHER INFORMATION		35
Item 1.	<u>Legal Proceedings</u>	35
Item 1A.	<u>Risk Factors</u>	37
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	38
Item 6.	<u>Exhibits</u>	39
<u>SIGNATURES</u>		43

## 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, 2007 and Part II, Item 1A – “Risk Factors” in this Form 10-Q.

Table of Contents

## PART I

## FINANCIAL INFORMATION

## Item 1. Condensed Consolidated Financial Statements

## CONDENSED CONSOLIDATED BALANCE SHEETS

(U.S. Dollars, in thousands except share data)	June 30, 2008 (Unaudited)	December 31, 2007 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,845	\$ 25,064
Restricted cash	11,709	16,453
Trade accounts receivable, net	119,097	108,900
Inventories, net	113,333	93,952
Deferred income taxes	11,373	11,373
Prepaid expenses and other current assets	28,858	25,035
Total current assets	301,215	280,777
Investments	4,427	4,427
Property, plant and equipment, net	35,255	33,444
Patents and other intangible assets, net	223,181	230,305
Goodwill	318,769	319,938
Deferred taxes and other long-term assets	16,750	16,773
Total assets	\$ 899,597	\$ 885,664
Liabilities and shareholders' equity		
Current liabilities:		
Bank borrowings	\$ 8,236	\$ 8,704
Current portion of long-term debt	3,340	3,343
Trade accounts payable	28,606	24,715
Other current liabilities	31,278	36,544
Total current liabilities	71,460	73,306
Long-term debt	289,242	294,588
Deferred income taxes	74,809	75,908
Other long-term liabilities	12,039	7,922
Total liabilities	447,550	451,724
Contingencies (Note 17)		
Shareholders' equity:		
Common shares (17,090,701 and 17,038,304 shares issued at June 30, 2008 and December 31, 2007, respectively)	1,710	1,704
Additional paid-in capital	163,944	157,349
Retained earnings	267,615	258,201
Accumulated other comprehensive income	18,778	16,686
Total shareholders' equity	452,047	433,940
Total liabilities and shareholders' equity	\$ 899,597	\$ 885,664

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



Table of ContentsCONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2008 AND 2007(Unaudited, U.S. Dollars, in thousands except share and  
per share data)

	Three Months Ended		Six Months Ended	
	2008	2007	2008	2007
Net sales	\$ 130,039	\$ 123,336	\$ 258,071	\$ 240,368
Cost of sales	35,048	33,008	69,286	63,804
Gross profit	94,991	90,328	188,785	176,564
Operating expenses				
Sales and marketing	53,246	47,310	103,442	91,893
General and administrative	18,779	16,806	40,959	32,711
Research and development	6,599	6,023	12,953	12,360
Amortization of intangible assets	4,830	4,571	9,873	9,039
Gain on sale of Pain Care® operations	-	-	(1,570)	-
	83,454	74,710	165,657	146,003
Operating income	11,537	15,618	23,128	30,561
Other income (expense)				
Interest (expense) income, net	(4,069)	(5,869)	(9,459)	(11,534)
Other, net	591	314	1,085	(242)
Other income (expense), net	(3,478)	(5,555)	(8,374)	(11,776)
Income before minority interests and income taxes	8,059	10,063	14,754	18,785
Minority interests	-	-	-	(43)
Income before income taxes	8,059	10,063	14,754	18,742
Income tax expense	(2,251)	(2,874)	(5,340)	(5,286)
Net income	\$ 5,808	\$ 7,189	\$ 9,414	\$ 13,456
Net income per common share - basic	\$ 0.34	\$ 0.43	\$ 0.55	\$ 0.82
Net income per common share - diluted	\$ 0.34	\$ 0.43	\$ 0.55	\$ 0.80
Weighted average number of common shares - basic	17,090,217	16,533,646	17,088,735	16,499,299
Weighted average number of common shares - diluted	17,116,015	16,819,166	17,240,004	16,852,769

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

Table of ContentsCONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE SIX MONTHS ENDED JUNE 30, 2008 AND 2007

(Unaudited, U.S. Dollars, in thousands)	2008	2007
Cash flows from operating activities:		
Net income	\$ 9,414	\$ 13,456
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	14,777	13,958
Amortization of debt costs	632	203
Provision for doubtful accounts	3,019	2,004
Deferred taxes	-	(3,103)
Share-based compensation	4,657	5,121
Minority interest	235	(10)
Amortization of step up of fair value in inventory	242	1,860
Gain on sale of Pain Care® operations	(1,570)	-
Other	515	(1,368)
Change in operating assets and liabilities:		
Restricted cash	4,772	(1,219)
Accounts receivable	(10,630)	(14,120)
Inventories	(16,734)	(15,682)
Prepaid expenses and other current assets	(4,486)	(2,890)
Accounts payable	3,250	2,265
Other current liabilities	(5,839)	1,282
Net cash provided by operating activities	2,254	1,757
Cash flows from investing activities:		
Payments made in connection with acquisitions and investments, net of cash acquired	-	(1,456)
Capital expenditures	(12,150)	(17,123)
Proceeds from sale of Pain Care® operations	5,980	-
Net cash used in investing activities	(6,170)	(18,579)
Cash flows from financing activities:		
Net proceeds from issue of common shares	1,922	2,964
Repayments of long-term debt	(5,351)	(5,649)
Proceeds from (repayments of) bank borrowings, net	(1,131)	8,438
Tax benefit on non-qualified stock options	22	694
Net cash (used in) provided by financing activities	(4,538)	6,447
Effect of exchange rate changes on cash	235	178
Net decrease in cash and cash equivalents	(8,219)	(10,197)
Cash and cash equivalents at the beginning of the year	25,064	25,881
Cash and cash equivalents at the end of the period	\$ 16,845	\$ 15,684

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

Table of Contents

NOTES TO THE CONDENSED UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: BUSINESS

Orthofix International N.V. (the “Company”) is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical devices, 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 six months ended June 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. The balance sheet at December 31, 2007 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. For further information, refer to the Consolidated Financial Statements and Notes thereto of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

NOTE 3: RECENTLY ISSUED ACCOUNTING STANDARDS

In December 2007, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1). EITF 07-1 provides guidance related to the classification of the payments between participants, the appropriate income statement presentation, as well as disclosures related to certain collaborative arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008 and will be adopted by the Company in the first quarter of 2009. Unless other authoritative guidance prevails, the Company will apply the guidance included in EITF 07-1 to collaborative arrangements entered into in 2008.

In May 2008, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 162, “The Hierarchy of Generally Accepted Accounting Principles.” The Statement identified the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. The Statement is effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, “The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.” We do not anticipate the adoption of SFAS No. 162 to have a material impact on the Company’s results of operations or financial position.

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements.” The Statement defines fair value, 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 provisions of SFAS No. 157 were to be effective for fiscal years beginning after November 15, 2007. On February 6, 2008, the FASB agreed to defer the effective date of SFAS No. 157 for one year for certain nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Effective



January 1, 2008, the Company adopted SFAS No. 157 except as it applies to those nonfinancial assets and nonfinancial liabilities. The adoption of SFAS No. 157 did not have a material impact on the Company's results of operations or financial position.

Effective January 1, 2008, the Company adopted SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FASB Statement No. 115." SFAS No. 159 allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement of certain financial assets and liabilities under an instrument-by-instrument election. Subsequent measurements for the financial assets and liabilities an entity elects to fair value will be recognized in the results of operations. SFAS No. 159 also establishes additional disclosure requirements. The Company did not elect the fair value option under SFAS No. 159 for any of its financial assets or liabilities upon adoption. The adoption of SFAS No. 159 did not have a material impact on the Company's results of operations or financial position.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133." SFAS No. 161 requires entities to provide greater transparency through additional disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, results of operations, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company is currently evaluating the potential impact of adopting SFAS No. 161 on the Company's disclosures of its derivative instruments and hedging activities.

Table of Contents

In December 2007, the FASB issued SFAS No. 141(R), “Business Combinations (revised 2007).” SFAS No. 141(R) amends SFAS No. 141, “Business Combinations,” and provides revised guidance for recognizing and measuring identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree. It also provides disclosure requirements to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008 and is to be applied prospectively. The Company is currently evaluating the potential impact of adopting SFAS No. 141(R) on its consolidated financial position and results of operations.

In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB 51,” which establishes accounting and reporting standards pertaining to ownership interest in subsidiaries held by parties other than the parent, the amount of net income attributable to the parent and to the noncontrolling interest, changes in a parent’s ownership interest, and the valuation of any retained noncontrolling equity investment when a subsidiary is deconsolidated. SFAS No. 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. The Company is currently evaluating the potential impact of adopting SFAS No. 160 on its consolidated financial position and results of operations.

## NOTE 4: SHARE-BASED COMPENSATION

The Company accounts for its share-based compensation plans in accordance with SFAS No. 123(R), “Share-Based Payment”, using the modified prospective transition method. Under SFAS No. 123(R), all share-based compensation costs are measured at the grant date, based on the estimated fair value of the award, and are recognized as expense in the statement of operations over the requisite service period. Commencing in June 2007, the Company offered restricted shares in addition to stock options as a form of share-based compensation.

The following table shows the detail of share-based compensation by line item in the Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2008 and 2007:

(In US\$ thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Cost of sales	\$ 79	\$ 91	\$ 192	\$ 180
Sales and marketing (1)	590	642	774	1,193
General and administrative	1,720	1,500	3,284	3,132
Research and development	174	289	407	616
Total	\$ 2,563	\$ 2,522	\$ 4,657	\$ 5,121

(1) There are no performance requirements and there was no consideration received for share-based compensation awarded to sales and marketing employees.

Table of Contents

## NOTE 5: RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform to the 2008 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.

Inventories were as follows:

(In US\$ thousands)	June 30, 2008	December 31, 2007
Raw materials	\$ 9,973	\$ 10,804
Work-in-process	7,755	6,100
Finished goods	61,352	42,384
Field inventory (as described above)	13,221	13,997
Consignment inventory	31,851	30,560
	124,152	103,845
Less reserve for obsolescence	(10,819)	(9,893)
	\$ 113,333	\$ 93,952

## NOTE 7: GOODWILL

The changes in the net carrying value of goodwill by reportable segment for the period ended June 30, 2008 are as follows:

(In US\$ thousands)	Domestic	Blackstone	Breg	International	Total
At December 31, 2007	\$ 31,793	\$ 136,240	\$ 101,322	\$ 50,583	\$ 319,938
Disposals (1)	-	-	(2,027)	-	(2,027)
Purchase price adjustment (2)	-	-	-	(365)	(365)
Foreign currency	-	-	-	1,223	1,223
At June 30, 2008	\$ 31,793	\$ 136,240	\$ 99,295	\$ 51,441	\$ 318,769

(1) Sale of operations relating to the Pain Care® business at Breg during the first quarter of 2008.

(2) Principally relates to the recording of inventory at fair value in connection with the acquisition of the remaining 38.74% of the minority interest in the Company's Mexican subsidiary during the first quarter of 2008.

Table of Contents

## NOTE 8: BANK BORROWINGS

(In US\$ thousands)	June 30, 2008	December 31, 2007
Borrowings under line of credit	\$ 8,236	\$ 8,704

The weighted average interest rates on borrowings under lines of credit as of June 30, 2008 and December 31, 2007 were 6.17% and 4.79%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 2.1 million Euros (\$3.3 million) and 1.3 million Euros (\$2.0 million) at June 30, 2008 and December 31, 2007, respectively, in its Italian line of credit, which gives the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing. This line of credit is unsecured.

## NOTE 9: LONG-TERM DEBT

(In US\$ thousands)	June 30, 2008	December 31, 2007
Long-term obligations	\$ 292,350	\$ 297,700
Other loans	232	231
	292,582	297,931
Less current portion	(3,340)	(3,343)
	\$ 289,242	\$ 294,588

On September 22, 2006 the Company's wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. ("Orthofix Holdings"), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. 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 June 30, 2008, the Company had no amounts outstanding under the revolving credit facility and \$292.4 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of the London Inter-Bank Offered Rate ("LIBOR") plus a margin or prime rate plus a margin. Currently, the term loan is a LIBOR loan, and the margin is 1.75%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. In June 2008, the Company entered into an interest rate swap agreement to manage its interest rate exposure on LIBOR borrowings; see Note 15, Derivative Instruments, for further detail. The effective interest rates as of June 30, 2008 and December 31, 2007 on the senior secured credit facility were 5.1% and 6.58%, respectively.

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

In conjunction with obtaining the senior secured credit facility and the amendment thereto, the Company incurred debt issuance costs of \$6.4 million. As of June 30, 2008, \$4.4 million of capitalized debt issuance costs are included in other long-term assets compared to \$5.2 million at December 31, 2007.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's senior secured credit facility. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company as parties to the credit agreement have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of June 30, 2008 is \$308.7 compared to \$300.7 million at December 31, 2007.

Table of Contents

In addition, the Company's senior secured credit facility 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 unless such breach is waived by the lenders, who are a party to the agreement, or the agreement is amended. Management believes the Company was in compliance with these financial covenants as measured at June 30, 2008.

However, in its second quarter earnings release, the Company has revised its operating expectations for the remainder of 2008 in part as a result of contract research and development obligations which it undertook for the development of new products. Based on the revised operating expectations, the Company expects to experience difficulty meeting these financial covenants for the remainder of 2008 as measured at September 30, 2008 and December 31, 2008. If the Company is unable to meet any of the financial covenants as measured at September 30, 2008 or December 31, 2008 (or any future quarterly measurement date), the Company intends to seek a waiver or amendment to the credit agreement. Any requested waivers or amendments to the credit agreement could result in fees or additional interest charged by the lenders for their approval. Although the Company believes we will be able to negotiate acceptable amendments or waivers, if necessary, there can be no assurance that we will be able to do so, and failure to do so could result in an event of default under credit agreement, which could have a material adverse effect on our financial position.

## NOTE 10: COMMON SHARES

For the six months ended June 30, 2008, the Company issued 52,397 shares of common stock upon the exercise of outstanding stock options, vesting of restricted stock, and shares issued pursuant to its employee stock purchase plan for net proceeds of \$1.9 million.

## NOTE 11: COMPREHENSIVE INCOME (LOSS)

Accumulated other comprehensive income (loss) 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 (loss) are as follows:

(In US\$ thousands)	Foreign Currency Translation Adjustments	Fair Value of Derivatives	Accumulated Other Comprehensive Income/(Loss)
Balance at December 31, 2007	\$ 15,156	\$ 1,530	\$ 16,686
Unrealized gain on derivative instruments, net of tax of \$848	-	1,921	1,921
Foreign currency translation adjustment	171	-	171
Balance at June 30, 2008	\$ 15,327	\$ 3,451	\$ 18,778

Table of Contents

(In US\$ thousands)	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2008	2007	2008	2007
Net income	\$ 5,808	\$ 7,189	\$ 9,414	\$ 13,456
Other comprehensive income:				
Unrealized (loss) gain on derivative instrument, net of tax	(903)	(5)	1,921	(208)
Foreign currency translation adjustment	1,798	(624)	171	1,473
Total comprehensive income	\$ 6,703	\$ 6,560	\$ 11,506	\$ 14,721

## NOTE 12: BUSINESS SEGMENT INFORMATION

The Company's segment information is prepared on the same basis that the Company's management reviews the financial information for operational decision making purposes. The Company is comprised of the following segments:

**Domestic**

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

**Blackstone**

Blackstone ("Blackstone") consists of Blackstone Medical, Inc., based in Springfield, Massachusetts and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Blackstone specializes in the design, development and marketing of spinal implant and related human cellular and tissue based products ("HCT/P products", often referred to as Biologic products). Blackstone's operating loss includes amortization of acquired intangible assets and in the second quarter of 2007, it also includes inventory which has been stepped-up in value for the Blackstone acquisition. Blackstone distributes its products through a network of domestic and international distributors, sales representatives and affiliates.

**Breg**

Breg ("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.

**International**

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

**Group Activities**

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

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





Table of Contents

For the three month period ended June 30:

(In US\$ thousands)	External Sales		Intersegment Sales	
	2008	2007	2008	2007
Domestic	\$ 47,205	\$ 41,632	\$ 1,683	\$ 1,290
Blackstone	26,924	30,017	1,064	735
Breg	21,901	20,193	1,118	751
International	34,009	31,494	7,935	7,736
Total	\$ 130,039	\$ 123,336	\$ 11,800	\$ 10,512

For the six month period ended June 30:

(In US\$ thousands)	External Sales		Intersegment Sales	
	2008	2007	2008	2007
Domestic	\$ 91,332	\$ 80,747	\$ 3,304	\$ 2,279
Blackstone	55,755	56,411	2,589	1,437
Breg	43,964	40,316	2,656	1,224
International	67,020	62,894	13,433	16,149
Total	\$ 258,071	\$ 240,368	\$ 21,982	\$ 21,089

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

Operating Income (Loss) (In US\$ thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Domestic	\$ 15,947	\$ 15,348	\$ 30,080	\$ 28,074
Blackstone	(6,985)	(734)	(10,792)	(1,348)
Breg	2,696	1,770	7,067	3,327
International	5,147	4,516	9,710	10,594
Group Activities	(4,401)	(4,410)	(12,216)	(7,909)
Eliminations	(867)	(872)	(721)	(2,177)
Total	\$ 11,537	\$ 15,618	\$ 23,128	\$ 30,561

Table of Contents

The following tables present sales by market sector for the three and six month periods ended June 30, 2008 and 2007:

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

(In US\$ thousands)	Orthofix Domestic	Blackstone	Breg	Orthofix International	Total
Spine	\$ 35,430	\$ 26,924	\$ -	\$ 358	\$ 62,712
Orthopedics	11,775	-	-	21,559	33,334
Sports Medicine	-	-	21,901	1,288	23,189
Vascular	-	-	-	3,741	3,741
Other	-	-	-	7,063	7,063
<b>Total</b>	<b>\$ 47,205</b>	<b>\$ 26,924</b>	<b>\$ 21,901</b>	<b>\$ 34,009</b>	<b>130,039</b>

Sales by Market Sector  
for the three month period ended June 30, 2007

(In US\$ thousands)	Orthofix Domestic	Blackstone	Breg	Orthofix International	Total
Spine	\$ 31,353	\$ 30,017	\$ -	\$ 102	\$ 61,472
Orthopedics	10,279	-	-	17,705	27,984
Sports Medicine	-	-	20,193	1,129	21,322
Vascular	-	-	-	5,578	5,578
Other	-	-	-	6,980	6,980
<b>Total</b>	<b>\$ 41,632</b>	<b>\$ 30,017</b>	<b>\$ 20,193</b>	<b>\$ 31,494</b>	<b>\$ 123,336</b>

Table of ContentsSales by Market Sector  
for the six month period ended June 30, 2008

(In US\$ thousands)	Orthofix Domestic	Blackstone	Breg	Orthofix International	Total
Spine	\$ 68,803	\$ 55,755	\$ -	\$ 612	\$ 125,170
Orthopedics	22,529	-	-	40,566	63,095
Sports Medicine	-	-	43,964	2,548	46,512
Vascular	-	-	-	9,117	9,117
Other	-	-	-	14,177	14,177
<b>Total</b>	<b>\$ 91,332</b>	<b>\$ 55,755</b>	<b>\$ 43,964</b>	<b>\$ 67,020</b>	<b>\$ 258,071</b>

Sales by Market Sector  
for the six month period ended June 30, 2007

(In US\$ thousands)	Orthofix Domestic	Blackstone	Breg	Orthofix International	Total
Spine	\$ 60,957	\$ 56,411	\$ -	\$ 253	\$ 117,621
Orthopedics	19,790	-	-	35,839	55,629
Sports Medicine	-	-	40,316	2,164	42,480
Vascular	-	-	-	10,499	10,499
Other	-	-	-	14,139	14,139
<b>Total</b>	<b>\$ 80,747</b>	<b>\$ 56,411</b>	<b>\$ 40,316</b>	<b>\$ 62,894</b>	<b>\$ 240,368</b>

## 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 primarily attributable to an unfavorable discrete tax item resulting from a taxable gain on the sale of the Company's Pain Care® operations. Further, the effective tax rate has been positively affected by the Company's European restructuring in 2006 and a similar transaction in 2002, whereby certain intangible assets were sold between subsidiaries in order to optimize the Company's supply chain. Such assets were sold at estimates of fair value based upon valuations which remain subject to review by the local taxing authorities. Further, the effective tax rate has been affected by the generation of un-utilizable net operating losses in various jurisdictions, and the Section 199 deduction related to income attributable to production activities occurring in the United States.

Table of Contents

As of June 30, 2008, the Company's gross unrecognized tax benefit was \$1.7 million plus \$0.5 million accrued for interest and penalties. The entire \$1.7 million of unrecognized tax benefit would affect the Company's effective tax rate if recognized. The Company believes it is reasonably possible that \$1.0 million of its gross unrecognized tax benefit will decrease during the twelve months ending December 31, 2008 if certain statutes of limitations expire during 2008.

The Company recognizes accrued interest and penalties related to unrecognized tax benefits within its global operations in income tax expense. To the extent interest and penalties are not assessed with respect to uncertain tax positions, amounts accrued will be reduced and reflected as a reduction of the overall income tax provision.

The Company is subject to tax examinations in all major taxing jurisdictions in which it operates. The Company files a consolidated income tax return in the U.S. federal jurisdiction and numerous consolidated and separate income tax returns in many state and foreign jurisdictions. The following table summarizes these open tax years by major jurisdiction:

Jurisdiction	Open Tax Year	
	Examination in Progress	Examination not yet Initiated
United States	2004-2006	2007
Various States	1996-2005	1996-2007
Brazil	N/A	2004-2007
Cyprus	N/A	2005-2007
France	N/A	2002-2007
Germany	2003-2005	2006-2007
Italy	N/A	2003-2007
Mexico	N/A	2000-2007
Netherlands	N/A	2004-2007
Puerto Rico	N/A	N/A
Seychelles	N/A	N/A
Switzerland	N/A	2004-2007
United Kingdom	N/A	2005-2007



Table of Contents

## NOTE 14:

## EARNINGS PER SHARE

For the three and six months ended June 30, 2008 and 2007, there were no adjustments to net income for purposes of calculating basic and diluted net income per common share. The following table is a reconciliation of the weighted average shares used in the basic and diluted net income per common share computations.

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2008	2007	2008	2007
Weighted average common shares - basic	17,090,217	16,533,646	17,088,735	16,499,299
Effect of dilutive securities	25,798	285,520	151,269	353,470
Weighted average common shares – diluted	17,116,015	16,819,166	17,240,004	16,852,769

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

For the three and six month periods ended June 30, 2007, the Company did not include 129,051 and 88,042 options, respectively, in the diluted shares outstanding calculation because their inclusion would have been anti-dilutive or because their exercise price exceeded the average market price of the Company's common stock during the period.

## NOTE 15:

## DERIVATIVE INSTRUMENTS

In June 2008, the Company entered into a three year fully amortizable interest rate swap agreement (the "Swap") with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of June 30, 2008 was \$150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of June 30, 2008 the interest rate on the debt related to the Swap was 5.5% (3.73% plus a margin of 1.75%). Our overall effective interest rate, including the impact of the Swap, as of June 30, 2008 on our senior secured debt was 5.1%. The instrument is designated as a cash flow hedge. The Company recognized the unrealized gain on the change in fair value of this swap arrangement of \$0.7 million, net of tax, within other comprehensive income for the three and six months ended June 30, 2008.

In 2006, the Company entered into a cross-currency swap agreement to manage its foreign currency exposure related to a portion of the Company's intercompany receivable of a U.S. dollar functional currency subsidiary that is denominated in Euro. The derivative instrument, a ten-year fully amortizable agreement with a notional amount of \$63.0 million is scheduled to expire on December 30, 2016. The instrument is designated as a cash flow hedge. The amount outstanding under the agreement as of June 30, 2008 is \$59.8 million. Under the agreement, the Company pays Euro and receives U.S. dollars based on scheduled cash flows in the agreement. The Company recognized an unrealized loss on the change in fair value of this swap arrangement of \$1.6 million, net of tax, within other comprehensive income for the three months ended June 30, 2008. The Company recognized the unrealized gain on the change in fair value of this swap arrangement of \$1.2 million, net of tax, within other comprehensive income for the six months ended June 30, 2008.



Table of Contents

## NOTE 16: FAIR VALUE MEASUREMENTS

As described in Note 3, “Recently Issued Accounting Standards,” the Company adopted SFAS No. 157 effective January 1, 2008. SFAS No. 157 defines fair value as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. SFAS No. 157 also describes three levels of inputs that may be used to measure fair value:

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

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

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

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

	Balance June 30, 2008	Level 1	Level 2	Level 3
Cash Equivalents	\$ 1,021	\$ 1,021	\$ -	\$ -
Derivative Financial Instruments(1)				
Cash Flow Hedges	\$ (7,224)	\$ -	\$ (7,224)	\$ -

(1) See Note 15, “Derivative Instruments”.

## NOTE 17: CONTINGENCIES

## Litigation

Effective October 29, 2007, the Company’s subsidiary, Blackstone, entered into a settlement agreement with respect to 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. In that lawsuit, the plaintiffs had alleged that (i) they were the exclusive licensees of United States Patent Nos. 6,926,718 B1, 6,936,050 B2, 6,936,051 B2, 6,398,783 B1 and 7,066,961 B2 (the “Patents”), and (ii) Blackstone's making, selling, offering for sale, and using within the United States of its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products infringed the Patents, and that such infringement was willful. The Complaint requested both damages and an injunction against further alleged infringement of the Patents. The Complaint did not specifically state an amount of damages. Blackstone denied infringement and asserted that the Patents were invalid. On July 20, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between the Company, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the “Merger Agreement”), for any losses to the Company or Blackstone resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the



Merger Agreement. The Company is unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund. The settlement agreement is not expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows.

Table of Contents

On or about July 23, 2007, Blackstone received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks documents for the period January 1, 2000 through July 31, 2006 which is prior to Blackstone's acquisition by the Company. The Company believes that the subpoena concerns the compensation of physician consultants and related matters. Blackstone is cooperating with the government's request and is in the process of responding to the subpoena. The Company is unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General or other governmental authorities as a result of this investigation or what impact, if any, the outcome of this matter might have on its consolidated financial position, results of operations, or cash flows. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to the Company or Blackstone resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. The Company is unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund.

On or about January 7, 2008, the Company received a federal grand jury subpoena from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks documents for the period January 1, 2000 through July 15, 2007 from the Company, including its subsidiaries. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters. The Company is cooperating with the government's request and is in the process of responding to the subpoena. The Company is unable to predict what action, if any, might be taken in the future by governmental authorities as a result of this investigation or what impact, if any, the outcome of this matter might have on its consolidated financial position, results of operations, or cash flows. It is the Company's intention to submit a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any recoverable losses to the Company or Blackstone resulting from this matter.

On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the United States' Attorney's Office for the District of Nevada ("USAO-Nevada"). The subpoena seeks documents for the period from January 1999 to the present. The Company believes that the subpoena concerns payments or gifts made by Blackstone to certain physicians. Blackstone is cooperating with the government's request and is in the process of responding to the subpoena. The Company is unable to predict what action, if any, might be taken in the future by the USAO-Nevada or other governmental authorities as a result of this investigation or what impact, if any, the outcome of this matter might have on its consolidated financial position, results of operations, or cash flows. It is the Company's intention to submit a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any recoverable losses to the Company or Blackstone resulting from this matter.

On February 29, 2008, Blackstone received a Civil Investigative Demand ("CID") from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. The Company believes that the CID seeks documents concerning Blackstone's financial relationships with certain physicians and related matters for the period from March 2004 through the date of issuance of the CID. The Company is cooperating with the government's request and is in the process of responding to the CID. It is the Company's intention to submit a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any recoverable losses to the Company or Blackstone resulting from this matter.

By order entered on January 4, 2007, the United States District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. A qui tam action is a civil lawsuit brought by an

individual for an alleged violation of a federal statute, in which the U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. The complaint alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan. On December 29, 2006, the U.S. Department of Justice filed a notice of non-intervention in the case. Plaintiff subsequently amended the complaint to add the Company as a defendant. On January 3, 2008, Dr. Chan pled guilty to one count of knowingly soliciting and receiving kickbacks from a medical device distributor in a criminal matter, in which neither the Company nor any of its business units or employees were defendants. In January 2008, Dr. Chan entered into a settlement agreement with the plaintiff and certain governmental entities in the civil qui tam action, and on February 21, 2008, a joint stipulation of dismissal of claims against Dr. Chan in the action was filed with the court, which removed him as a defendant in the action. On July 11, 2008, the court granted a motion to dismiss the Company as a defendant in the action. Blackstone remains a defendant. The Company believes that Blackstone has meritorious defenses to the claims alleged and we intend to defend vigorously against this lawsuit. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to the Company or Blackstone resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. The Company is unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund.

Table of Contents

Between January 2007 and May 2007, Blackstone and Orthofix Inc. were named defendants, along with other medical device manufacturers, in three civil lawsuits alleging that Dr. Chan had performed unnecessary surgeries in three different instances. In January 2008, the Company learned that Orthofix Inc. was named a defendant, along with other medical device manufacturers, in a fourth civil lawsuit alleging that Dr. Chan had performed unnecessary surgeries. All four civil lawsuits have been served and are pending in the Circuit Court of White County, Arkansas. The Company believes that the Company and its subsidiaries have meritorious defenses to the claims alleged and the Company and its subsidiaries intend to defend vigorously against these lawsuits. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to the Company or Blackstone resulting from one of these four civil lawsuits. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. The Company is unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund.

Of the total Blackstone purchase price, approximately \$50.0 million was placed into an escrow account. As described in the Agreement and Plan of Merger, the Company can make claims for reimbursement from the escrow account for certain defined items relating to the acquisition for which the Company is indemnified. As described in Note 17, the Company has certain contingencies arising from the acquisition that management expects will be reimbursable from the escrow account should the Company have to make a payment to a third party. The Company records the claims against the escrow in an escrow receivable account which is included in other current assets on the consolidated balance sheets. Because the Company believes that the settlement process of escrow claims is complex and all claims may not be reimbursed, management has recorded a partial reserve against the escrow receivable. Further, management believes that the amount that it will be required to pay relating to the contingencies will not exceed the amount of the escrow account; however, there can be no assurance that the contingencies will not exceed the amount of the escrow account.

In addition to the foregoing claims, the Company has submitted claims for indemnification from the escrow fund established in connection with the Merger Agreement for losses that have or may result from certain claims against Blackstone alleging that plaintiffs and/or claimants were entitled to payments for Blackstone stock options not reflected in Blackstone's corporate ledger at the time of Blackstone's acquisition by the Company. To date, the representative of the former shareholders of Blackstone has not objected to approximately \$1.5 million in claims from the escrow fund, with certain claims remaining pending.

The Company cannot predict the outcome of any proceedings or claims made against the Company or its subsidiaries and there can be no assurance that the ultimate resolution of any claim will not have a material adverse impact on its consolidated financial position, results of operations, or cash flows.

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

United Kingdom Payroll Taxes

In 2007, Intavent Orthofix Limited, the Company's UK distribution subsidiary, received an inquiry from H.M. Revenue and Customs (HMRC) relating to the tax treatment of gains made by UK employees on the exercise of stock options. The Company is in the process of formulating a response to HMRC. Based on preliminary calculations, a provision of \$0.5 million has been provided, of which the Company has paid \$0.2 million. The Company cannot predict the ultimate outcome of its discussions with HMRC.



Table of Contents

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 fiscal year ended December 31, 2007.

NOTE 18:

SUBSEQUENT EVENTS

On July 24, 2008, the Company entered into an agreement with Musculoskeletal Transplant Foundation ("MTF") to collaborate on the development and commercialization of a new stem cell-based bone growth biologic matrix. Under the terms of the agreement, the Company will invest up to \$10.0 million in the development of the new stem cell-based bone growth biologic matrix that will be designed to provide the beneficial properties of an autograft in spinal and orthopedic surgeries. After the completion of the development process, the Company and MTF will operate under the terms of a separate commercialization agreement. Under the terms of this 10-year agreement, MTF will source the tissue, process it to create the bone growth matrix, and package and deliver it in accordance with orders received directly from customers and from the Company. The Company will have exclusive global marketing rights for the new allograft and will receive a marketing fee from MTF based on total sales. The Company intends to account for this collaborative arrangement under guidance included in Emerging Issues Task Force Issue No. 07-1 "Accounting for Collaborative Arrangements," unless more authoritative guidance applies. The Company currently plans for the new matrix to be launched in the U.S. during 2009.

Table of Contents

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

The following discussion and analysis addresses our liquidity, financial condition, and the results of our operations for the three and six months ended June 30, 2008 compared to our results of operations for the three and six months ended June 30, 2007. These discussions should be read in conjunction with our historical consolidated financial statements and related notes thereto and the other financial information included in this Form 10-Q and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

General

We are a diversified orthopedic products company offering a broad line of surgical and non-surgical products for the Spine, Orthopedics, Sports Medicine and Vascular market sectors. Our products are designed to address the lifelong bone-and-joint health needs of patients of all ages, helping them achieve a more active and mobile lifestyle. We design, develop, manufacture, market and distribute medical equipment used principally by musculoskeletal medical specialists for orthopedic applications. Our main products are invasive and minimally invasive spinal implant products and related human cellular and tissue based products ("HCT/P products"), non-invasive bone growth stimulation products used to enhance the success rate of spinal fusions and to treat non-union fractures, external and internal fixation devices used in fracture treatment, limb lengthening and bone reconstruction; and bracing products used for ligament injury prevention, pain management and protection of surgical repair to promote faster healing. Our products also include a device for enhancing venous circulation, cold therapy, bone cement and devices for removal of bone cement used to fix artificial implants and airway management products used in anesthesia applications.

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

Our condensed consolidated financial statements include the financial results of the Company and its wholly-owned and majority-owned subsidiaries and entities over which we have control. All intercompany accounts and transactions are eliminated in consolidation.

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

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

On September 22, 2006, we completed the acquisition of Blackstone Medical, Inc. (“Blackstone”), a privately held company specializing in the design, development and marketing of spinal implant and related HCT/P products. The purchase price for the acquisition was \$333.0 million, subject to certain closing adjustments, plus transaction costs and other accruals totaling approximately \$12.6 million as of June 30, 2008. The acquisition and related costs were financed with \$330.0 million of senior secured term debt and cash on hand. Financing costs were approximately \$6.4 million.



Table of Contents

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

## Segment and Market Sector Revenues

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

## Business Segment:

(In US\$ thousands)	Three Months Ended June 30,			
	2008		2007	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	\$ 47,205	36%	\$ 41,632	34%
Blackstone	26,924	21%	30,017	24%
Breg	21,901	17%	20,193	16%
International	34,009	26%	31,494	26%
Total	\$ 130,039	100%	\$ 123,336	100%

(In US\$ thousands)	Six Months Ended June 30,			
	2008		2007	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	\$ 91,332	35%	\$ 80,747	34%
Blackstone	55,755	22%	56,411	23%
Breg	43,964	17%	40,316	17%
International	67,020	26%	62,894	26%
Total	\$ 258,071	100%	\$ 240,368	100%

Table of Contents

Market Sector:

(In US\$ thousands)	Three Months Ended June 30,			
	2008		2007	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Spine	\$ 62,712	48%	\$ 61,472	50%
Orthopedics	33,334	26%	27,984	23%
Sports Medicine	23,189	18%	21,322	17%
Vascular	3,741	3%	5,578	4%
Other	7,063	5%	6,980	6%
Total	\$ 130,039	100%	\$ 123,336	100%

(In US\$ thousands)	Six Months Ended June 30,			
	2008		2007	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Spine	\$ 125,170	49%	\$ 117,621	49%
Orthopedics	63,095	24%	55,629	23%
Sports Medicine	46,512	18%	42,480	18%
Vascular	9,117	4%	10,499	4%
Other	14,177	5%	14,139	6%
Total	\$ 258,071	100%	\$ 240,368	100%

Table of Contents

The following table presents certain items from our Condensed Consolidated Statements of Operations as a percent of total net sales for the periods indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008 (%)	2007 (%)	2008 (%)	2007 (%)
Net sales	100	100	100	100
Cost of sales	27	27	27	27
Gross profit	73	73	73	73
Operating expenses				
Sales and marketing	41	38	40	38
General and administrative	14	14	16	14
Research and development	5	5	5	5
Amortization of intangible assets	4	4	4	4
Gain on sale of Pain Care® operations	-	-	(1)	-
Total operating income	9	13	9	13
Net income	4	6	4	6

## Three Months Ended June 30, 2008 Compared to Three Months Ended June 30, 2007

Net sales increased 5% to \$130.0 million for the second quarter of 2008 compared to \$123.3 million for the second quarter of 2007. The impact of foreign currency increased sales by \$2.9 million during the second quarter of 2008 as compared to the second quarter of 2007.

## Sales by Business Segment:

Net sales in Domestic increased to \$47.2 million in the second quarter of 2008 compared to \$41.6 million in the second quarter of 2007, an increase of 13%. Domestic's net sales represented 36% of total net sales during the second quarter of 2008 and 34% of total net sales for the second quarter of 2007. The increase in Domestic's net sales was partially the result of a 13% increase in sales in our Spine market sector, which was mainly driven by the increase in sales of our Spinal-Stim® and Cervical-Stim® products. The increase in Domestic's net sales can also be attributed to the 15% increase in our Orthopedic market sector as sales of our Physio-Stim® products increased 15% when compared to the second quarter of 2007. These increases were slightly offset by a 1% decrease in sales of external fixation products.

## Domestic Sales by Market Sector:

(In US\$ thousands)	Net Sales for the Three Months Ended June 30,		Growth
	2008	2007	
Spine	\$ 35,430	\$ 31,353	13%
Orthopedics	11,775	10,279	15%
Total	\$ 47,205	\$ 41,632	13%



Table of Contents

Net sales in Blackstone decreased \$3.1 million to \$26.9 million in the second quarter of 2008 compared to \$30.0 million in the second quarter of 2007, a decrease of 10%. Blackstone's net sales represented 21% of total net sales during the second quarter of 2008 and 24% during the second quarter of 2007. During the integration of Blackstone into our business we have experienced substantial turnover of sales management and distributors which has negatively impacted our sales during the quarter. Sales may continue to be negatively impacted until the new distributors are established in selling Blackstone products. These decreases have been partially offset by the increase in sales attributable to our human cellular and tissue based products ("HCT/P products", often referred to as Biologic products). All of Blackstone's sales are recorded in our Spine market sector.

Net sales in Breg increased \$1.7 million to \$21.9 million in the second quarter of 2008 compared to \$20.2 million for the second quarter of 2007, an increase of 8%. Breg's net sales represented 17% of total net sales during the second quarter of 2008 and 16% of total net sales during the same period in 2007. The increase in Breg's net sales was primarily due to a 17% increase in sales of our cold therapy products when compared to the same period in the prior year. Further, sales of our Breg® bracing products increased 13% from the second quarter of 2007, primarily as a result of the sales of our Fusion XT™ products. These increases were partially offset by a decrease in sales of our pain therapy products as a result of the sale of operations related to our Pain Care® line of ambulatory infusion pumps during March 2008. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International increased 8% to \$34.0 million in the second quarter of 2008 compared to \$31.5 million in the second quarter of 2007. International's net sales represented 26% of our total net sales in the second quarter of both 2008 and 2007. The impact of foreign currency increased International net sales by 9% or \$2.7 million, during the second quarter of 2008 as compared to the second quarter of 2007. International net sales were positively impacted by an increase in sales of our Orthopedic products which increased by 22% as compared to the second quarter of 2007 primarily as a result of the sales of our internal fixation products including the eight-Plate Guided Growth System®, which increased 80%, as well as increased sales of our OSCAR, Physio-Stim® and Cemex® products. Further, sales of Breg products within International, included in the Sports Medicine sector, increased 14% when compared to second quarter of 2007. Offsetting these increases, International sales in our Vascular sector, which consists of the A-V Impulse System®, decreased \$1.8 million or 33% from the second quarter of 2007 as our principal distributor for the product, who is based in the United States, sought to reduce their inventory balances. Sales are expected to return to higher historic levels in the second half of 2008. Sales of distributed products, which includes the Laryngeal Mask, remained constant at approximately \$7.1 million.

## International Sales by Market Sector:

(In US\$ thousands)	Net Sales for the		
	Three Months Ended June 30,		Growth
	2008	2007	
Spine	\$ 358	\$ 102	251%
Orthopedics	21,559	17,705	22%
Sports Medicine	1,288	1,129	14%
Vascular	3,741	5,578	(33)%
Other	7,063	6,980	1%
<b>Total</b>	<b>\$ 34,009</b>	<b>\$ 31,494</b>	<b>8%</b>

## Sales by Market Sector:

Sales of our Spine products increased 2% to \$62.7 million in the second quarter of 2008 compared to \$61.5 million in the second quarter of 2007. The increase of \$1.2 million is primarily due to a 17% increase in sales of Cervical-Stim® products as well as a 10% increase in sales of Spinal-Stim® products in the United States. These increases were offset with a 9% decrease in sales of Blackstone products from the second quarter of 2007 as a result of substantial turnover of sales management and distributors in Blackstone as previously discussed. Spine product sales were 48% and 50% of our total net sales in the second quarter of 2008 and 2007, respectively.

## Table of Contents

Sales of our Orthopedic products increased 19% to \$33.3 million in the second quarter of 2008 compared to \$28.0 million in the second quarter of 2007. The increase of \$5.4 million can be primarily attributed to a 16% increase in sales of our Physio-Stim® products and a 50% increase in sales of our internal fixation devices including the eight-Plate Guided Growth System®. Orthopedic product sales were 26% and 23% of our total net sales in the second quarter of 2008 and 2007, respectively.

Sales of our Sports Medicine products increased 9% to \$23.2 million in the second quarter of 2008 compared to \$21.3 million in the second quarter of 2007. As discussed above, the increase of \$1.9 million is primarily due to sales of our Breg® cold therapy and bracing products, offset by a decrease in our pain therapy products, which can be mainly attributed to the sale of operations relating to our Pain Care® line in March 2008. Sports Medicine product sales were 18% and 17% of our total net sales in the second quarter of 2008 and 2007, respectively.

Sales of our Vascular products, which consist of our A-V Impulse System®, decreased 33% to \$3.7 million in the second quarter of 2008 compared to \$5.6 million in the second quarter of 2007 as our principal distributor for the product, who is based in the United States, sought to reduce their inventory balances. Vascular product sales were 3% and 4% of our total net sales in the second quarter of 2008 and 2007, respectively.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our Woman's Care line, increased 1% to \$7.1 million in the second quarter of 2008 as compared to \$7.0 million in the second quarter of 2007. Other product sales were 5% and 6% of our total net sales in the second quarter of 2008 and 2007, respectively.

Gross Profit - Our gross profit increased 5% to \$95.0 million in the second quarter of 2008, from \$90.3 million in the second quarter of 2007. The improvement in gross profit can be primarily attributed to increased sales, as discussed above. Sales of our spinal stimulation products, which are our higher margin products, were up 13% from the same period in the prior year. These increased margins were offset by a decline in the margins of Blackstone's products mainly due to the impact of a changing sales mix with a higher percentage of overall sales coming from lower profit Blackstone international distributors and Blackstone domestic sales of HCT/P products. Gross profit as a percent of net sales in the second quarter of 2008 and 2007 was 73.0% compared to 73.2% in the second quarter of 2007.

Sales and Marketing Expense - Sales and marketing expense, which includes commissions, royalties and the bad debt provision, increased \$5.9 million, or 13%, to \$53.2 million in the second quarter of 2008 compared to \$47.3 million in the second quarter of 2007. This increase is attributed to increased expense in order to support increased sales activity, including higher commissions on higher sales, higher commissions as a result of higher commission rates and guaranteed minimum commissions, and additional sales and marketing structure at Blackstone. As a percent of sales, sales and marketing expense was 40.9% in the second quarter of 2008 compared to 38.4% in the second quarter of 2007.

General and Administrative Expense - General and administrative expense increased \$2.0 million, or 12%, in the second quarter of 2008 to \$18.8 million compared to \$16.8 million in the second quarter of 2007. The increase was primarily attributable to approximately \$0.7 million related to corporate reorganizations. In addition, corporate overhead costs, including finance, accounting and legal costs increased when compared to the prior year. General and administrative expense as a percent of sales was 14.4% in the second quarter of 2008 compared to 13.6% in the second quarter of 2007.

Research and Development Expense - Research and development expense increased \$0.6 million in the second quarter of 2008 to \$6.6 million compared to \$6.0 million in the second quarter of 2007, primarily as a result of increased product development spending at Blackstone. As a percent of sales, research and development expense was 5.1% in the second quarter of 2008 compared to 4.9% in the second quarter of 2007. For the remainder of 2008, research and

development expenses are expected to increase as a result of the agreements the Company entered into with Musculoskeletal Transplant Foundation (“MTF”) and Intelligent Implant Systems, LLC (“IIS”). We expect to incur up to \$10.8 million of expense related to these agreements in 2008; see Liquidity and Capital Resources for further details.



Table of Contents

Amortization of Intangible Assets – Amortization of intangible assets increased \$0.3 million, or 6%, in the second quarter of 2008 to \$4.8 million compared to \$4.6 million in the second quarter of 2007. This increase can be primarily attributed to an increase in the rate of amortization at Blackstone associated with definite-lived intangible assets obtained in the Blackstone acquisition in September 2006.

Interest Income (Expense), net – Interest expense, net was \$4.1 million for the second quarter of 2008 compared to \$5.9 million for the second quarter of 2007. Interest expense for the second quarters of 2008 and 2007 included interest expense of \$3.3 million and \$5.6 million, respectively, related to the senior secured term loan used to finance the Blackstone acquisition. This decrease can be mainly attributed to a lower interest rate as well as less principal from the comparable period in the prior year.

Other, net – Other, net was income of \$0.6 million for the second quarter of 2008 compared to income of \$0.3 million for the second quarter of 2007. The increase can be mainly attributed to the effect of foreign exchange.

Income Tax Expense – Our estimated worldwide effective tax rates were 27.9% and 28.6% during the second quarters of 2008 and 2007, respectively. The effective tax rate for the second quarter of 2008 was positively affected by less income in the United States, a higher tax jurisdiction.

Net Income – Net income for the second quarter of 2008 was \$5.8 million, or \$0.34 per basic and diluted share, compared to net income of \$7.2 million, or \$0.43 per basic share and per diluted share, for the second quarter of 2007. The weighted average number of basic common shares outstanding was 17,090,217 and 16,533,646 during the second quarters of 2008 and 2007, respectively. The weighted average number of diluted common shares outstanding was 17,116,015 and 16,819,166 during the second quarters of 2008 and 2007, respectively.

Six Months Ended June 30, 2008 Compared to Six Months Ended June 30, 2007

Net sales increased 7% to \$258.1 million for the first six months of 2008 compared to \$240.4 million for the first six months of 2007. The impact of foreign currency increased sales by \$5.2 million during the first six months of 2008 as compared to the first six months of 2007.

Sales by Business Segment:

Net sales in Domestic increased to \$91.3 million in the first six months of 2008 compared to \$80.7 million in the first six months of 2007, an increase of 13%. Domestic's net sales represented 35% of total net sales during the first six months of 2008 and 34% of total net sales for the first six months of 2007. The increase in Domestic's net sales was partially the result of a 13% increase in sales in our Spine market sector, which was mainly driven by the increase in sales of our Spinal-Stim® and Cervical-Stim® products. The increase in Domestic's net sales can also be attributed to the 14% increase in our Orthopedic market sector as sales of our internal fixation products including our eight-Plate Guided Growth System® increased 12%, and sales of our Physio-Stim® products increased 12% when compared to the first six months of 2007. These increases were partially offset by a 5% decrease in sales of external fixation products when compared to the same period in the prior year.

Table of Contents

## Domestic Sales by Market Sector:

(In US\$ thousands)	Net Sales for the		Growth
	2008	2007	
Spine	\$ 68,803	\$ 60,957	13%
Orthopedics	22,529	19,790	14%
Total	\$ 91,332	\$ 80,747	13%

Net sales in Blackstone decreased to \$55.8 million in the first six months of 2008 compared to \$56.4 million in the first six months of 2007, a decrease of 1%. Blackstone's net sales represented 22% of total net sales during the first six months of 2008 and 23% during the first six months of 2007. During the integration of Blackstone into our business we have experienced substantial turnover of sales management and distributors which has negatively impacted our sales during the first six months. Our sales may continue to be negatively impacted by this turnover until the new distributors are established in selling Blackstone products. These decreases in sales have been partially offset by the increase in sales of our human cellular and tissue based products ("HCT/P products", often referred to as Biologic products). All of Blackstone's sales are recorded in our Spine market sector.

Net sales in Breg increased \$3.6 million to \$44.0 million in the first six months of 2008 compared to \$40.3 million for the first six months of 2007, an increase of 9%. Breg's net sales represented 17% of total net sales during the first six months of 2008 and 2007. The increase in Breg's net sales was primarily due to an increase in the sales of our Breg® bracing products which increased 14% from the first six months of 2007, primarily as a result of the sales of our Fusion XT™ products. Further, sales of our cold therapy products increased 15% when compared to the same period in the prior year. These increases were partially offset by a decrease in sales of our pain therapy products as a result of the sale of operations related to our Pain Care® line of ambulatory infusion pumps during March 2008. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International increased 7% to \$67.0 million in the first six months of 2008 compared to \$62.9 million in the first six months of 2007. International's net sales represented 26% of our total net sales in the first six months of 2008 and 2007. The impact of foreign currency increased International net sales by 8% or \$5.0 million, during the first six months of 2008 as compared to the first six months of 2007. The sales of our Orthopedic products increased by 13% as compared to the first six months of 2007 primarily as a result of the sales of our internal fixation products including the eight-Plate Guided Growth System®, which increased 42%, as well as increased sales of our OSCAR and Physio-Stim® products. Further, sales of Breg products within International, included in the Sports Medicine sector, increased 18% when compared to the first six months of 2007. International sales in our Vascular sector, which consists of the A-V Impulse System®, decreased \$1.4 million or 13% from the first six months of 2007, as our principal distributor for the product, who is based in the United States, sought to reduce their inventory balances. Sales are expected to return to higher historic levels in the second half of 2008. Sales of distributed products, which includes the Laryngeal Mask, remained constant.

Table of Contents

## International Sales by Market Sector:

(In US\$ thousands)	Net Sales for the Six Months Ended June 30,		Growth
	2008	2007	
Spine	\$ 612	\$ 253	142%
Orthopedics	40,566	35,839	13%
Sports Medicine	2,548	2,164	18%
Vascular	9,117	10,499	(13)%
Other	14,177	14,139	--%
<b>Total</b>	<b>\$ 67,020</b>	<b>\$ 62,894</b>	<b>7%</b>

## Sales by Market Sector:

Sales of our Spine products increased 6% to \$125.2 million in the first six months of 2008 compared to \$117.6 million in the first six months of 2007. The increase of \$7.5 million is primarily due to a 13% increase in sales of spinal stimulation products in the United States. Spine product sales were 49% of our total net sales in the first six months of both 2008 and 2007.

Sales of our Orthopedic products increased 13% to \$63.1 million in the first six months of 2008 compared to \$55.6 million in the first six months of 2007. The increase of \$7.5 million can be mainly attributed to a 32% increase in sales of our internal fixation devices including the eight-Plate Guided Growth System®. Further, the 13% increase in sales of our Physio-Stim® products also contributed to the increase in our Orthopedic sales. Offsetting these increases, our external fixation product sales decreased by 2%, from the first six months of 2007. Orthopedic product sales were 24% and 23% of our total net sales in the first six months of 2008 and 2007, respectively.

Sales of our Sports Medicine products increased 9% to \$46.5 million in the first six months of 2008 compared to \$42.5 million in the first six months of 2007. As discussed above, the increase of \$4.0 million is primarily due to sales of our Breg® bracing products as well as our cold therapy products, offset by a decrease in our pain therapy products, which can be mainly attributed to the sale of operations relating to our Pain Care® line in March 2008. Sports Medicine product sales were 18% of our total net sales in the first six months of both 2008 and 2007.

Sales of our Vascular products, which consist of our A-V Impulse System®, decreased 13% to \$9.1 million in the first six months of 2008 compared to \$10.5 million in the first six months of 2007. Sales decreased as our principal distributor for the product in the United States sought to reduce their inventory balances. Sales are expected to return to higher historic levels in the second half of 2008. Vascular product sales were 4% of our total net sales in the first six months of both 2008 and 2007.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our Woman's Care line, remained flat at approximately \$14.2 million in the first six months of 2008 as compared to \$14.1 million in the first six months of 2007. Other product sales were 5% and 6% of our total net sales in the first six months of 2008 and 2007, respectively.

Table of Contents

**Gross Profit** - Our gross profit increased 7% to \$188.8 million in the first six months of 2008, from \$176.6 million in the first six months of 2007. The improvement in gross profit can be primarily attributed to increased sales, as discussed above. Sales of our spinal stimulation products, which are our higher margin products, were up 13% from the same period in the prior year. These increased margins were offset by a decline in the margins of Blackstone's products mainly due to the impact of a changing sales mix with a higher percentage of overall sales coming from lower profit Blackstone international distributors and Blackstone domestic sales of HCT/P products. Further, during the six months of 2007, we recorded a charge of \$1.9 million for amortization of the step-up in inventory associated with the Blackstone acquisition. Since the step-up in the Blackstone inventory from purchase accounting was fully amortized during 2007, no such amortization was recorded during the first six months of 2008. Gross profit as a percent of net sales in the first six months of 2008 was 73.2% compared to 73.4% in the first six months of 2007.

**Sales and Marketing Expense** - Sales and marketing expense, which includes commissions, royalties and the bad debt provision, increased \$11.5 million, or 13%, to \$103.4 million in the first six months of 2008 compared to \$91.9 million in the first six months of 2007. This increase is attributed to increased expense in order to support increased sales activity, including higher commissions on higher sales, higher commissions as a result of higher commission rates and guaranteed minimum commissions, and additional sales and marketing structure at Blackstone. In addition, sales and marketing expense increased due to costs incurred related to the completed exploration of the potential divestiture of our orthopedic fixation business. Offsetting these increases, SFAS 123(R) expense decreased \$0.4 million from the comparable period in the prior year. As a percent of sales, sales and marketing expense was 40.1% in the first six months of 2008 compared to 38.2% in the first six months of 2007.

**General and Administrative Expense** - General and administrative expense increased \$8.2 million, or 25%, in the first six months of 2008 to \$41.0 million compared to \$32.7 million in the first six months of 2007. The increase was primarily attributable to a charge of \$2.8 million recorded in the first half of 2008 related to the completed exploration of the potential divestiture of our orthopedic fixation business, as well as increased audit fees and headcount, especially at our Brazilian and Blackstone subsidiaries. General and administrative expense as a percent of sales was 15.9% in the first six months of 2008 compared to 13.6% in the first six months of 2007.

**Research and Development Expense** - Research and development expense increased \$0.6 million in the first six months of 2008 to \$13.0 million compared to \$12.4 million in the first six months of 2007, primarily as a result of increased product development spending at Blackstone. As a percent of sales, research and development expense was 5.0% in the first six months compared with 5.1% in the first six months of 2007. For the remainder of 2008, research and development expenses are expected to increase as a result of the agreements the Company entered into with MTF and IIS. We expect to incur up to \$10.8 million of expense related to these agreements in 2008; see Liquidity and Capital Resources for further details.

**Amortization of Intangible Assets** - Amortization of intangible assets increased approximately \$0.8 million, or 9%, in the first six months of 2008 to \$9.9 million compared to \$9.0 million in the first six months of 2007. This increase can be primarily attributed to an increase in the rate of amortization at Blackstone associated with definite-lived intangible assets obtained in the Blackstone acquisition in September 2006.

**Gain on Sale of Pain Care® Operations** - Gain on sale of Pain Care® operations was \$1.6 million in the first six months of 2008 and represented the gain on the sale of operations related to our Pain Care® line of ambulatory infusion pumps during March 2008. No such gain was recorded in the first six months of 2007.

**Interest Income (Expense), net** - Interest expense, net was \$9.5 million for the first six months of 2008 compared to \$11.5 million for the first six months of 2007. Interest expense for the first six months of 2008 and 2007 included interest expense of \$8.3 million and \$11.2 million, respectively, related to the senior secured term loan used to finance the Blackstone acquisition. This decrease can be mainly attributed to a lower interest rate as well as less principal

from the comparable period in the prior year.

Other, net – Other, net was income of \$1.1 million for the first six months of 2008 compared to expense of \$0.2 million for the first six months of 2007. The increase can be mainly attributed to the effect of foreign exchange.

Income Tax Expense – Our estimated worldwide effective tax rates were 36.2% and 28.2% during the first six months of 2008 and 2007, respectively. The effective tax rate for the first six months of 2008 included an unfavorable discrete item resulting from the sale of operations related to our Pain Care® operations. Excluding this discrete item, our effective rate was 29.9%. The effective tax rate for the first six months of 2008 was also negatively affected by the expiration of a U.K. tax planning strategy and the generation of unutilizable net operating losses in various jurisdictions.

Table of Contents

Net Income – Net income for the first six months of 2008 was \$9.4 million, or \$0.55 per basic and diluted share, compared to net income of \$13.5 million, or \$0.82 per basic share and \$0.80 per diluted share, for the first six months of 2007. The weighted average number of basic common shares outstanding was 17,088,735 and 16,499,299 during the first six months of 2008 and 2007, respectively. The weighted average number of diluted common shares outstanding was 17,240,004 and 16,852,769 during the first six months of 2008 and 2007, respectively.

Liquidity and Capital Resources

Cash and cash equivalents at June 30, 2008 were \$28.6 million, of which \$11.7 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$41.5 million at December 31, 2007, of which \$16.5 million was restricted.

Net cash provided by operating activities increased to \$2.3 million for the first six months of 2008 compared to \$1.8 million provided by operating activities in the first six months of 2007. Net cash provided by operating activities is comprised of net income, non-cash items (including share-based compensation and non-cash purchase accounting items from the Blackstone and Breg acquisitions) and changes in working capital, including changes in restricted cash. Net income decreased \$4.0 million to \$9.4 million for the first six months of 2008 from net income of \$13.5 million for the comparable period in the prior year. Non-cash items for the first six months of 2008 increased \$3.8 million from the first six months of 2007 primarily as a result of an increase in the provision for bad debts which was partially offset by the \$1.6 million gain on the sale of the operations related to the Breg Pain Care® line. Working capital accounts consumed \$29.7 million of cash in the first six months of 2008 compared to \$30.4 million in the same period in 2007. The principal uses of cash for working capital can be mainly attributable to 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 83 days at June 30, 2008 compared to 87 days at June 30, 2007 and inventory turns of 1.2 times at June 30, 2008 compared to 1.5 times at June 30, 2007. The lower inventory turns and resultant higher inventory balances reflect purchases to support Blackstone sales, support for new spinal implant and internal fixation products, and support for additional supply of Biologics products.

Net cash used in investing activities was \$6.2 million during the first six months of 2008 compared to \$18.6 million used in investing activities during the first six months of 2007. During the first half of 2008, we sold the operations of our Pain Care® line of ambulatory infusion pumps for net proceeds of \$6.0 million. In the six months ended June 30, 2008, we invested \$12.2 million in capital expenditures, of which \$7.3 million were related to Blackstone and included the acquisition of intellectual property and related technology for a next generation spinal fixation system from IIS. During the first six months of 2007, we invested \$17.1 million in capital expenditures of which \$10.4 million were related to Blackstone. We also invested \$1.5 million in subsidiaries and affiliates which was a result of adjustments in purchase accounting related to Blackstone and a purchase of a minority interest in our subsidiary in Mexico.

Net cash used in financing activities was \$4.5 million in the first six months of 2008 compared to \$6.4 million provided in the same period of 2007. During the first six months of 2008, we repaid approximately \$5.4 million against the principal on our senior secured term loan and repaid \$1.1 million to support working capital in our Italian subsidiary. In addition, we received proceeds of \$1.9 million from the issuance of 52,397 shares of our common stock upon the exercise of stock options and shares issued pursuant to the employee stock purchase plan. During the first six months of 2007, we repaid \$5.6 million against the principal on our senior secured term loan and borrowed \$8.4 million to support working capital in our Italian subsidiary. In addition, we received proceeds of \$3.0 million from the issuance of 98,907 shares of our common stock upon the exercise of stock options.



Table of Contents

On September 22, 2006 our wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. (“Orthofix Holdings”), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. 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 June 30, 2008 we had no amounts outstanding under the revolving credit facility and \$292.4 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of the London Inter-Bank Offered Rate (“LIBOR”) plus a margin or prime rate plus a margin. Currently, the term loan is a LIBOR loan, and the margin is 1.75%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. In June 2008, the Company entered into a three year fully amortizable interest rate swap agreement (the “Swap”) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of June 30, 2008 was \$150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of June 30, 2008 the interest rate on the debt related to the Swap was 5.5% (3.73% plus a margin of 1.75%). Our overall effective interest rate, including the impact of the Swap, as of June 30, 2008 on our senior secured debt was 5.1%.

Our senior secured credit facility contains certain financial covenants, including a fixed charge coverage ratio and a leverage ratio applicable to Orthofix and our subsidiaries on a consolidated basis. A breach of any of these covenants could result in an event of default under the credit agreement, which could permit acceleration of the debt payments under the facility unless such breach is waived by the lenders, who are a party to the agreement, or the agreement is amended. Management believes the Company was in compliance with these financial covenants as measured at June 30, 2008.

However, in our second quarter earnings release, has revised its operating expectations for the remainder of 2008, in part, as a result of contract research and development obligations which we undertook for the development of new products. Based on the revised operating expectations, we expect to experience difficulty meeting these financial covenants for the remainder of 2008 as measured at September 30, 2008 and December 31, 2008. If we are unable to meet any of the financial covenants as measured at September 30, 2008 or December 31, 2008 (or any future quarterly measurement date), we intend to seek a waiver or amendment to the credit agreement. Any requested waivers or amendments to the credit agreement could result in fees or additional interest charged by the lenders for their approval. Although the Company believes we will be able to negotiate acceptable amendments or waivers, if necessary, there can be no assurance that we will be able to do so, and failure to do so could result in an event of default under credit agreement, which could have a material adverse effect on our financial position.

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

At June 30, 2008, we had outstanding borrowings of \$8.2 million and unused available lines of credit of approximately 2.1 million Euro (\$3.3 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

We 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.



As discussed in Note 18 “Subsequent Events” in the Condensed Consolidated Financial Statements, we have entered into a collaborative agreement with Musculoskeletal Transplant Foundation (“MTF”) to develop and commercialize a new stem cell-based bone growth biologic matrix. Under the terms of the agreement, we will invest up to \$10.0 million in the development of the new stem cell-based bone growth biologic matrix that will be designed to provide the beneficial properties of an autograft in spinal and orthopedic surgeries. We have also entered into an agreement with IIS, as mentioned above, where we have purchased \$2.5 million of intellectual property and related technology. IIS will continue to perform research and development functions related to the technology and under the agreement, we will pay IIS an additional amount, up to \$4.5 million for research and development performance milestones. We believe that current cash balances together with projected cash flows from operating activities, the available Italian line of credit, and our debt capacity are sufficient to cover anticipated working capital and capital expenditure needs including research and development costs and research and development projects formerly mentioned, over the near term.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations, and the cost of financing and yields on cash and short-term investments. We use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of June 30, 2008, we had a currency swap in place to minimize foreign currency exchange risk related to a 42.6 million Euro intercompany note foreign currency exposure.

We are exposed to interest rate risk in connection with our senior secured term loan and borrowings under our revolving credit facility, which bear interest at floating rates based on LIBOR or the prime rate plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant. We had an interest rate swap in place as of June 30, 2008 to minimize interest rate risk related to our LIBOR-based borrowings.

As of June 30, 2008, we had \$292.4 million of variable rate term debt represented by borrowings under our senior secured term loan at a floating interest rate of LIBOR plus a margin or the 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. In June 2008, the Company entered into a Swap with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of June 30, 2008 was \$150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of June 30, 2008 the interest rate on the debt related to the Swap was 5.5% (3.73% plus a margin of 1.75%). Our overall effective interest rate, including the impact of the Swap, as of June 30, 2008 on our senior secured debt was 5.1%. Based on the balance outstanding under the senior secured term loan combined with the Swap as of June 30, 2008, 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 \$1.4 million on an annual basis.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Great Britain Pound, Mexican Peso and Brazilian Real. We are subject to cost of goods currency exposure when we produce products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. As of June 30, 2008, we had an uncovered intercompany receivable denominated in Euro for approximately \$11.4 million. We recorded a foreign currency gain during the first six months of 2008 of \$0.2 million which resulted from the strengthening of the Euro against the U.S. dollar during the period.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the first six months of 2008 and 2007 by foreign currency exchange rate fluctuations with the weakening of the U.S dollar against the local foreign currency during these periods. The U.S. dollar equivalent of the related costs denominated in these foreign currencies was unfavorably impacted during these periods. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results.



Table of Contents

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a - 15(e) or 15d - 15 (e)) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2008 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

## PART II

## OTHER INFORMATION

## Item 1. Legal Proceedings

Effective October 29, 2007, our subsidiary, Blackstone, entered into a settlement agreement with respect to 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. In that lawsuit, the plaintiffs had alleged that (i) they were the exclusive licensees of United States Patent Nos. 6,926,718 B1, 6,936,050 B2, 6,936,051 B2, 6,398,783 B1 and 7,066,961 B2 (the "Patents"), and (ii) Blackstone's making, selling, offering for sale, and using within the United States of its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products infringed the Patents, and that such infringement was willful. The Complaint requested both damages and an injunction against further alleged infringement of the Patents. The Complaint did not specifically state an amount of damages. Blackstone denied infringement and asserted that the Patents were invalid. On July 20, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between the Company, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the "Merger Agreement"), for any losses to us resulting from this matter. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. We are unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to us from the escrow fund. The settlement agreement is not expected to have a material impact on our consolidated financial position, results of operations or cash flows.

On or about July 23, 2007, Blackstone received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks documents for the period January 1, 2000 through July 31, 2006 which is prior to Blackstone's acquisition by the Company. We believe that the subpoena concerns the compensation of physician consultants and related matters. Blackstone is cooperating with the government's request and is in the process of responding to the subpoena. We are unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General or other governmental authorities as a result of this investigation or what impact, if any, the outcome of this matter might have on our consolidated financial position, results of operations, or cash flows. On September 17, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from this matter. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. We are unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to us from the escrow fund.

On or about January 7, 2008, the Company received a federal grand jury subpoena from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks documents for the period January 1, 2000 through July 15, 2007 from us. We believe that the subpoena concerns the compensation of physician consultants and related matters, and further believe that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters. We are cooperating with the government's request and are in the process of responding to the subpoena. We are unable to predict what action, if any, might be taken in the future by governmental authorities as a result of this investigation or what impact, if any, the outcome of this matter might have on our consolidated financial position, results of operations, or cash flows. It is our intention to submit a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any recoverable losses to us or Blackstone resulting from this matter.

On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the United States Attorney's Office for the District of Nevada ("USAO-Nevada"). The subpoena seeks documents for the period from January 1999 to the present. We believe that the subpoena concerns payments or gifts made by Blackstone to certain physicians. Blackstone is cooperating with the government's request and is in the process of responding to the subpoena. We are unable to predict what action, if any, might be taken in the future by the USAO-Nevada or other governmental authorities as a result of this investigation or what impact, if any, the outcome of this matter might have on our consolidated financial position, results of operations, or cash flows. It is our intention to submit a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any recoverable losses to us or Blackstone resulting from this matter.

Table of Contents

On February 29, 2008, Blackstone received a Civil Investigative Demand (“CID”) from the Massachusetts Attorney General’s Office, Public Protection and Advocacy Bureau, Healthcare Division. We believe that the CID seeks documents concerning Blackstone’s financial relationships with certain physicians and related matters for the period from March 2004 through the date of issuance of the CID. We are cooperating with the government’s request and are in the process of responding to the CID. It is our intention to submit a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any recoverable losses to us or Blackstone resulting from this matter.

By order entered on January 4, 2007, the United States District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. A qui tam action is a civil lawsuit brought by an individual for an alleged violation of a federal statute, in which the U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. The complaint alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan. On December 29, 2006, the U.S. Department of Justice filed a notice of non-intervention in the case. Plaintiff subsequently amended the complaint to add Orthofix International N.V. as a defendant. On January 3, 2008, Dr. Chan pled guilty to one count of knowingly soliciting and receiving kickbacks from a medical device distributor in a criminal matter in which neither the Company nor any of its business units or employees were defendants. In January 2008, Dr. Chan entered into a settlement agreement with the plaintiff and certain governmental entities in the civil qui tam action, and on February 21, 2008, a joint stipulation of dismissal of claims against Dr. Chan in the action was filed with the court, which removed him as a defendant in the action. On July 11, 2008, the court granted a motion to dismiss the Company as a defendant in the action. Blackstone remains a defendant. The Company believes that Blackstone has meritorious defenses to the claims alleged and we intend to defend vigorously against this lawsuit. On September 17, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from this matter. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. We are unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to us from the escrow fund.

Between January 2007 and May 2007, Blackstone and Orthofix Inc. were named defendants, along with other medical device manufacturers, in three civil lawsuits alleging that Dr. Chan had performed unnecessary surgeries in three different instances. In January 2008, we learned that Orthofix Inc. was named a defendant, along with other medical device manufacturers, in a fourth civil lawsuit alleging that Dr. Chan had performed unnecessary surgeries. All four civil lawsuits have been served and are pending in the Circuit Court of White County, Arkansas. We believe that we have meritorious defenses to the claims alleged and we intend to defend vigorously against these lawsuits. On September 17, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from one of these four civil lawsuits. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. We are unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to us from the escrow fund.

In addition to the foregoing claims, we have submitted claims for indemnification from the escrow fund established in connection with the Merger Agreement for losses that have or may result from certain claims against Blackstone alleging that plaintiffs and/or claimants were entitled to payments for Blackstone stock options not reflected in Blackstone's corporate ledger at the time of Blackstone's acquisition by the Company. To date, the representative of the former shareholders of Blackstone have not objected to approximately \$1.5 million in claims from the escrow fund, with certain claims remaining pending.





## Table of Contents

We cannot predict the outcome of any proceedings or claims made against the Company or its subsidiaries and there can be no assurance that the ultimate resolution of any claim will not have a material adverse impact on our consolidated financial position, results of operations, or cash flows.

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

### Item 1A. Risk Factors

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

When we acquired Blackstone on September 22, 2006, one of our wholly-owned subsidiaries, Orthofix Holdings, Inc. (Orthofix Holdings), entered into a senior secured bank credit facility with a syndicate of financial institutions to finance the transaction. Orthofix and certain of Orthofix Holdings' 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 for which \$292.4 million was outstanding at June 30, 2008, and (2) a six-year revolving credit facility of \$45.0 million upon which we had not drawn as of June 30, 2008.

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. Management believes the Company was in compliance with these financial covenants as measured at June 30, 2008.

However, in its second quarter earnings release, the Company has revised its operating expectations for the remainder of 2008, in part as a result of contract research and development obligations which it undertook for the development of new products. Based on the revised operating expectations, the Company expects to experience difficulty meeting these financial covenants for the remainder of 2008 as measured at September 30, 2008 and December 31, 2008. If the Company is unable to meet any of the financial covenants as measured at September 30, 2008 or December 31, 2008 (or any future quarterly measurement date), the Company intends to seek a waiver or amendment to the credit agreement. Any requested waivers or amendments to the credit agreement could result in fees or additional interest charged by the lenders for their approval. Although the Company believes we will be able to negotiate acceptable amendments or waivers, if necessary, there can be no assurance that we will be able to do so, and failure to do so could result in an event of default under credit agreement, which could have a material adverse effect on our financial position. 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.

The senior secured bank credit facility requires mandatory prepayments that may have an adverse effect on our operations and limit our ability to grow our business

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, as of the end of any fiscal year, there will be no mandatory excess cash flow prepayments, with respect to such fiscal year (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.

Table of Contents

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

The Annual General Meeting of Shareholders of the Company was held on June 19, 2008. The total number of common shares eligible to vote as of the record date, April 23, 2008, was 17,088,856 and pursuant to the Company's Articles of Association, 8,544,428 constituted a quorum. The total number of common shares actually voted was 15,293,378.

At the Annual General Meeting:

1. The following persons were elected by a plurality of the votes cast at the meeting as Directors of the Company for a one year term expiring at the Annual General Meeting in 2008:

Name	Votes For	Votes Withheld
Jerry C. Benjamin	14,499,235	794,143
Charles W. Federico	13,381,904	1,911,474
James F. Gero	13,695,729	1,697,649
Peter J. Hewett	13,067,564	2,225,814
Guy J. Jordan	13,942,046	1,351,332
Thomas J. Kester	14,489,677	803,701
Alan W. Milinazzo	13,694,449	1,598,929
Maria Sainz	14,540,731	752,647
Walter P. Von Wartburg	14,529,542	763,836
Kenneth R. Weisshaar	14,633,039	760,339

2. Amendment No. 1 to the Amended and Restated 2004 Long Term Incentive Plan was approved by a vote of 7,562,912 in favor, 6,644,943 against and 3,790 abstaining; and
3. The Orthofix International N.V. Amended and Restated Stock purchase plan was approved by a vote of 13,778,350 in favor, 429,144 against and 4,151 abstaining; and
4. The proposal to amend Article 8.3 of the Articles of Association of the Company were approved and ratified by a vote of 13,944,325 in favor, 1,289,908 against and 9,147 abstaining and;
5. The audited Financial Statements and the Annual Report 2007 for the year ended December 31, 2007 were adopted and approved by a vote of 14,850,792 in favor, 2,931 against and 439,655 abstaining; and
6. The selection of Ernst & Young LLP to act as independent registered public accounting firm for the Company and its subsidiaries for the fiscal year ending December 31, 2008 was ratified by a vote of 15,032,878 in favor, 255,322 against and 5,476 abstaining.

Table of Contents

## Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
<u>3.2*</u>	Articles of Association of the Company as amended.
<u>10.1*</u>	Orthofix International N.V. Amended and Restated Stock Purchase Plan.
10.2	Orthofix International N.V. Staff Share Option Plan, as amended through April 22, 2003 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007 and incorporated herein by reference).
10.3	Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed June 26, 2007 and incorporated herein by reference).
10.4	Amendment No. 1 to the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.5	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (vesting over 3 years) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.6	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff vesting) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.7	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (vesting over 3 years) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.8	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff vesting) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.9	Orthofix Deferred Compensation Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2006, as amended, and incorporated herein by reference).

- 10.10 Employment Agreement, dated as of April 15, 2005, between the Company 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).
- 10.11 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).

Table of Contents

10.12*	Description of July 2008 Modifications to Employment Arrangement with Bradley R. Mason
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	Amended and Restated Voting and Subscription Agreement dated as of December 22, 2003, among Orthofix International N.V. and the significant shareholders of Breg, Inc. identified on the signature pages thereto (filed as an exhibit to the Company's current report on Form 8-K filed on January 8, 2004 and incorporated herein by reference).
10.15	Amendment to Employment Agreement dated December 29, 2005 between Orthofix Inc. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed December 30, 2005 and incorporated herein by reference).
10.16	Form of Indemnity Agreement (filed as an exhibit to the Company's annual report on Form 10-K filed 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 annual report on Form 8-K filed on April 17, 2006 and incorporated herein by reference).
10.18	Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.19	Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.20	Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Michael M. Finegan. (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.21	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 Limited, Blackstone Medical, Inc. and William G. Lyons, III, as Equityholders' Representative (filed as an exhibit to the Company's current report on Form 8-K filed August 7, 2006 and incorporated herein by reference).

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

Table of Contents

10.24	Amended and Restated Employment Agreement dated December 6, 2007 between Orthofix Inc. and Timothy M. Adams (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.25	Letter Agreement between Orthofix International N.V. and Bradley R. Mason dated November 20, 2007 (filed as an exhibit to the Company's current report on Form 8-K filed November 21, 2007 and incorporated herein by reference).
10.26	Amended and Restated Performance Accelerated Stock Option Agreement between Orthofix International N.V. and Bradley R. Mason dated November 20, 2007 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.27	Nonqualified Stock Option Agreement between Timothy M. Adams and Orthofix International N.V. dated November 19, 2007 (filed as an exhibit to the Company's current report on Form 8-K filed November 21, 2007 and incorporated herein by reference).
10.28	Employment Agreement between Orthofix Inc. and Oliver Burckhardt, dated as of December 11, 2007 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.29	Employment Agreement between Orthofix Inc. and Scott Dodson, dated as of December 10, 2007 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.30	Employment Agreement between Orthofix Inc. and Michael Simpson, dated as of December 6, 2007 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.31	Description of Director Fee Policy (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.32	Summary of Orthofix International N.V. Annual Incentive Program (filed as an exhibit to the Company's current report on Form 8-K filed April 11, 2008, and incorporated herein by reference).
10.33	Employment Agreement between Orthofix Inc. and Thomas Hein dated as of April 11, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).
10.34	Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan, dated April 11, 2008, between Orthofix International N.V. and Thomas Hein (filed as an exhibit to the Company's quarterly



report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).

- 10.35 Summary of Consulting Arrangement between Orthofix International N.V. and Peter Hewett (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).

10.36\* Employment Agreement between Orthofix Inc. and Denise E. Pedulla dated as of June 9, 2008.

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.

42

---

Table of Contents

SIGNATURES

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

ORTHOFIX INTERNATIONAL N.V.

Date: August 8, 2008

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

Date: August 8, 2008

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