

ORTHOFIX INTERNATIONAL N V  
Form 10-Q  
November 10, 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 September 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

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

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 November 7, 2008, 17,101,718 shares of common stock were issued and outstanding.

---

---

---

## Table of Contents

## PART I FINANCIAL INFORMATION

Item 1.	<u>Condensed Consolidated Financial Statements</u>	3
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	23
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	37
Item 4.	<u>Controls and Procedures</u>	38
PART II OTHER INFORMATION		
Item 1.	<u>Legal Proceedings</u>	39
Item 1A.	<u>Risk Factors</u>	41
Item 6.	<u>Exhibits</u>	43
<u>SIGNATURES</u>		47

## Forward-Looking Statements

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

Factors that could cause actual results to differ materially from those indicated by the forward-looking statements or that could contribute to such differences include, but are not limited to, risks relating to the expected sales of products, including recently launched products, unanticipated expenditures, changing relationships with customers, suppliers, strategic partners and lenders, unfavorable results in litigation matters, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, changes to and interpretation of governmental regulation of medical devices, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry and the economy, currency or interest rate fluctuations, corporate development and marketing development activities, including acquisitions and divestitures, unexpected costs or operating unit performance related to recent acquisitions, unexpected difficulties meeting covenants under our senior secured bank credit facility and the other risks described under Item 1A – “Business – Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 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)	September 30, 2008 (Unaudited)	December 31, 2007 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,286	\$ 25,064
Restricted cash	16,761	16,453
Trade accounts receivable, net	115,679	108,900
Inventories, net	97,368	93,952
Deferred income taxes	11,373	11,373
Prepaid expenses and other current assets	30,059	25,035
Total current assets	281,526	280,777
Investments, at cost	2,095	4,427
Property, plant and equipment, net	33,154	33,444
Patents and other intangible assets, net	55,354	230,305
Goodwill	187,353	319,938
Deferred taxes and other long-term assets	19,305	16,773
Total assets	\$ 578,787	\$ 885,664
Liabilities and shareholders' equity		
Current liabilities:		
Bank borrowings	\$ 6,197	\$ 8,704
Current portion of long-term debt	3,337	3,343
Trade accounts payable	26,561	24,715
Other current liabilities	33,361	36,544
Total current liabilities	69,456	73,306
Long-term debt	288,370	294,588
Deferred income taxes	5,475	75,908
Other long-term liabilities	5,630	7,922
Total liabilities	368,931	451,724
Contingencies (Note 18)		
Shareholders' equity:		
Common shares (17,101,718 and 17,038,304 shares issued at September 30, 2008 and December 31, 2007, respectively)	1,710	1,704
Additional paid-in capital	166,954	157,349
Retained earnings	30,364	258,201
Accumulated other comprehensive income	10,828	16,686
Total shareholders' equity	209,856	433,940
Total liabilities and shareholders' equity	\$ 578,787	\$ 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 NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007(Unaudited, U.S. Dollars, in thousands except share and  
per share data)

	Three Months Ended		Nine Months Ended	
	2008	2007	2008	2007
Net sales	\$ 129,301	\$ 121,120	\$ 387,372	\$ 361,488
Cost of sales	47,998	30,742	117,284	94,546
Gross profit	81,303	90,378	270,088	266,942
Operating expenses				
Sales and marketing	50,210	47,055	153,652	138,949
General and administrative	19,293	16,908	60,252	49,619
Research and development	6,447	5,953	19,400	18,313
Amortization of intangible assets	5,347	4,671	15,220	13,710
Impairment of goodwill and certain intangible assets	289,523	-	289,523	-
Gain on sale of Pain Care® operations	-	-	(1,570)	-
	370,820	74,587	536,477	220,591
Operating income (loss)	(289,517)	15,791	(266,389)	46,351
Other income (expense), net				
Interest expense, net	(4,249)	(5,666)	(13,708)	(17,200)
Loss on refinancing of senior secured term loan	(5,735)	-	(5,735)	-
Other, net	(3,822)	519	(2,737)	234
	(13,806)	(5,147)	(22,180)	(16,966)
Income (loss) before income taxes	(303,323)	10,644	(288,569)	29,385
Income tax (expense) benefit	66,072	(2,616)	60,732	(7,902)
Net (loss) income	\$ (237,251)	\$ 8,028	\$ (227,837)	\$ 21,483
Net income (loss) per common share - basic	\$ (13.87)	\$ 0.48	\$ (13.33)	\$ 1.30
Net income (loss) per common share - diluted	\$ (13.87)	\$ 0.48	\$ (13.33)	\$ 1.27
Weighted average number of common shares -basic	17,101,718	16,639,019	17,093,133	16,546,385
Weighted average number of common shares - diluted	17,101,718	16,889,303	17,093,133	16,925,084

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

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

(Unaudited, U.S. Dollars, in thousands)	2008	2007
Cash flows from operating activities:		
Net income (loss)	\$ (227,837)	\$ 21,483
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	22,707	21,334
Amortization of debt costs	868	523
Provision for doubtful accounts	4,585	3,532
Deferred taxes	(76,861)	(3,919)
Share-based compensation	7,855	8,006
Change in inventory obsolescence estimate	10,913	-
Loss on refinancing of senior secured term loan	3,660	-
Impairment of goodwill and certain intangible assets	289,523	-
Impairment of investments held at cost	1,500	-
Amortization of step up of fair value in inventory	365	2,718
Gain on sale of Pain Care® operations	(1,570)	-
Other	3,062	(1,328)
Change in operating assets and liabilities:		
Restricted cash	(352)	(4,270)
Accounts receivable	(13,805)	(14,829)
Inventories	(16,703)	(19,086)
Prepaid expenses and other current assets	(5,250)	(5,976)
Accounts payable	2,500	(2,707)
Other current liabilities	(2,739)	8,277
Net cash provided by operating activities	2,421	13,758
Cash flows from investing activities:		
Payments made in connection with acquisitions and investments in subsidiaries, net of cash acquired	(501)	(2,117)
Capital expenditures	(15,831)	(23,752)
Proceeds from sale of investment held at cost	766	-
Proceeds from sale of Pain Care® operations	5,980	-
Net cash used in investing activities	(9,586)	(25,869)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	1,734	6,799
Repayments of long-term debt, net	(6,223)	(6,505)
Proceeds from (repayments of) bank borrowings, net	(2,377)	7,870
Payment of refinancing fees	(283)	-
Tax benefit on non-qualified stock options	22	1,164
Net cash (used in) provided by financing activities	(7,127)	9,328
Effect of exchange rate changes on cash	(486)	464
Net decrease in cash and cash equivalents	(14,778)	(2,319)
Cash and cash equivalents at the beginning of the year	25,064	25,881
Cash and cash equivalents at the end of the period	\$ 10,286	\$ 23,562

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

5

---



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 nine months ended September 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.

Table of Contents

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.

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.

Table of Contents

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

(In US\$ thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Cost of sales	\$ -	\$ 113	\$ 116	\$ 293
Sales and marketing (1)	579	800	1,353	1,993
General and administrative	2,433	1,846	5,793	4,978
Research and development	186	126	593	742
<b>Total</b>	<b>\$ 3,198</b>	<b>\$ 2,885</b>	<b>\$ 7,855</b>	<b>\$ 8,006</b>

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

## 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: INVENTORIES

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

Inventories were as follows:

(In US\$ thousands)	September 30, 2008	December 31, 2007
Raw materials	\$ 9,302	\$ 10,804
Work-in-process	6,998	6,100
Finished goods	57,840	42,384
Field inventory (as described above)	12,368	13,997
Consignment inventory	33,563	30,560
	120,071	103,845
Less reserve for obsolescence	(22,703)	(9,893)

\$ 97,368 \$ 93,952

In the quarter ended September 30, 2008, due to reduced projections in revenue, distributor terminations, new products, and the replacement of one product with a successor product, the Company changed its estimates regarding the inventory allowance at Blackstone, primarily based on estimated net realizable value using assumptions about future demand and market conditions. The change in estimate resulted in an increase in the reserve for obsolescence of approximately \$10.9 million (\$7.0 million net of tax or \$0.41 per basic and diluted share).

8

---

Table of Contents

## NOTE 7: GOODWILL

The changes in the net carrying value of goodwill by reportable segment for the period ended September 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)	-	-	-	(248)	(248)
Impairment (3)	-	(126,873)	-	-	(126,873)
Foreign currency	-	-	-	(3,437)	(3,437)
At September 30, 2008	\$ 31,793	\$ 9,367	\$ 99,295	\$ 46,898	\$ 187,353

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

(2) Principally relates to the acquisition of the remaining 38.74% of the minority interest in the Company's Mexican subsidiary and the remaining 10.5% of the minority interest in the Company's Brazilian subsidiary during the first and third quarters of 2008, respectively.

(3) In accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," the Company performed an impairment analysis of indefinite-lived intangibles. As part of the Company's debt refinancing completed in September 2008, five year projections were prepared for Blackstone. Due to the recent trend of decreasing revenues at Blackstone, the Company evaluated the goodwill at Blackstone. The fair value of the Blackstone reporting unit was estimated using a combination of the income approach, which estimates the fair value of the reporting units based on the expected present value of future cash flows and the market approach, which estimates the fair value of the reporting units based on comparable market prices. The impairment analysis resulted in a goodwill impairment charge of \$126.9 million because the carrying value exceeded the implied fair value of goodwill.

## NOTE 8: PATENTS AND OTHER INTANGIBLE ASSETS

(In US\$ thousands)	September 30, 2008	December 31, 2007
Cost		
Patents and other	\$ 33,233	\$ 107,235
Trademarks – definite lived (subject to amortization)	682	714
Trademarks – indefinite lived (not subject to amortization)	23,876	80,844
Distribution networks	44,586	98,586
	102,377	287,379
Accumulated amortization		
Patents and other	(20,826)	(28,254)

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

Trademarks – definite lived (subject to amortization)	(657)	(559)
Distribution networks	(25,540)	(28,261)
	\$ 55,354	\$ 230,305

9

---

Table of Contents

Amortization expense for intangible assets is estimated to be approximately \$2.4 million for the remainder of 2008 and \$8.5 million, \$7.8 million, \$7.2 million, \$6.8 million and \$5.9 million for the periods ending December 31, 2009, 2010, 2011, 2012, and 2013 respectively.

During the third quarter of 2008, the Company determined that a test for impairment of goodwill in accordance with SFAS No. 142 “Goodwill and Other Intangible Assets,” was necessary due to Blackstone projections prepared in connection with the Company’s debt refinancing completed in September 2008, being materially different than projections used in Blackstone’s original purchase accounting. The Company evaluated the indefinite-lived intangible assets which included the Blackstone Trademark acquired during the acquisition of Blackstone. The impairment analysis resulted in the carrying value of the Trademark exceeding the fair value for which there is a \$57.0 million impairment charge included in Impairment of Goodwill and Certain Intangible Assets.

Also, during the third quarter of 2008, the Company determined that a Triggering Event as defined by SFAS No. 144 “Accounting for the Impairment or Disposal of Long-Lived Assets” occurred with respect to the definite-lived intangibles at Blackstone. Due to the Triggering Event, the Company compared the expected cash flows to be generated by the definite-lived intangibles on an undiscounted basis to the carrying value of the intangible asset. The Company determined the carrying value exceeded the undiscounted cash flow and impaired the distribution network and technologies at Blackstone to their fair value which resulted in an impairment charge of \$105.7 million which is included in Impairment of Goodwill and Certain Intangible Assets.

## NOTE 9: BANK BORROWINGS

(In US\$ thousands)	September 30, 2008	December 31, 2007
Borrowings under line of credit	\$ 6,197	\$ 8,704

The weighted average interest rates on borrowings under lines of credit as of September 30, 2008 and December 31, 2007 were 6.97% and 4.79%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 2.9 million Euros (\$4.1 million) and 1.3 million Euros (\$2.0 million) at September 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 10: LONG-TERM DEBT

(In US\$ thousands)	September 30, 2008	December 31, 2007
Long-term obligations	\$ 291,525	\$ 297,700
Other loans	182	231
	291,707	297,931
Less current portion	(3,337)	(3,343)
	\$ 288,370	\$ 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. Certain terms of the senior secured credit facility were amended September 29, 2008. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million, the proceeds of which, together with cash balances were used for payment of the purchase price of Blackstone; and (2) a six-year revolving credit facility of \$45.0 million. As of September 30, 2008, the Company had no amounts outstanding under the revolving credit facility and \$291.5 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 4.50%, 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 16, Derivative Instruments, for further detail. The effective interest rates as of September 30, 2008 and December 31, 2007 on the senior secured credit facility were 8.2% and 6.6%, respectively.

Table of Contents

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, the Company incurred debt issuance costs of \$6.4 million which it has been amortizing over the life of the facility. A portion of the capitalized debt issuance costs included in other long-term assets related to the senior secured credit facility were expensed as a result of the amendment on September 29, 2008, and are included in the loss on refinancing of senior secured term loan. In connection with the amendment to the credit facility, the Company paid additional fees of \$2.4 million in the quarter ended September 30, 2008, of which \$2.1 million are included in the loss on refinancing of senior secured term loan. As of September 30, 2008, \$0.8 million of debt issuance costs which relate to the Company's revolving credit facility are included in other long-term assets compared to debt issuance costs related to the senior secured term loan and the revolving credit facility which were \$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 September 30, 2008 is \$6.4 million compared to \$300.7 million at December 31, 2007.

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 September 30, 2008.

NOTE 11:

COMMON SHARES

For the nine months ended September 30, 2008, the Company issued 63,414 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 \$1.7 million.

NOTE 12:

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 cash flow hedges. The components of and changes in other comprehensive income (loss) are as follows:

Table of Contents

(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 loss on derivative instruments, net of tax of \$(71)	-	(76)	(76)
Foreign currency translation adjustment	(5,782)	-	(5,782)
Balance at September 30, 2008	\$ 9,374	\$ 1,454	\$ 10,828

(In US\$ thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net (loss) income	\$ (237,251)	\$ 8,028	\$ (227,837)	\$ 21,483
Other comprehensive income:				
Unrealized loss on derivative instrument, net of tax	(1,997)	(367)	(76)	(575)
Foreign currency translation adjustment	(5,953)	1,227	(5,782)	2,699
Total comprehensive income (loss)	\$ (245,201)	\$ 8,888	\$ (233,695)	\$ 23,607

## NOTE 13: BUSINESS SEGMENT INFORMATION

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

**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 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.



Table of Contents

## 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 nine month periods ended September 30:

For the three month period ended September 30:

(In US\$ thousands)	External Sales		Intersegment Sales	
	2008	2007	2008	2007
Domestic	\$ 47,065	\$ 41,971	\$ 1,552	\$ 858
Blackstone	25,338	29,448	349	1,012
Breg	22,377	21,206	1,392	1,337
International	34,521	28,495	6,240	5,958
Total	\$ 129,301	\$ 121,120	\$ 9,533	\$ 9,165

For the nine month period ended September 30:

(In US\$ thousands)	External Sales		Intersegment Sales	
	2008	2007	2008	2007
Domestic	\$ 138,397	\$ 122,718	\$ 4,856	\$ 3,137
Blackstone	81,093	85,859	2,938	2,449
Breg	66,341	61,522	4,048	2,561
International	101,541	91,389	19,673	22,108
Total	\$ 387,372	\$ 361,488	\$ 31,515	\$ 30,255

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

Table of Contents

Operating Income (Loss) (In US\$ thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Domestic	\$ 17,155	\$ 14,050	\$ 47,235	\$ 42,124
Blackstone (1)	(309,201)	(816)	(319,993)	(2,164)
Breg	2,206	2,686	9,273	6,013
International	4,741	4,230	14,451	14,824
Group Activities	(4,309)	(3,735)	(16,525)	(11,644)
Eliminations	(109)	(624)	(830)	(2,802)
Total	\$ (289,517)	\$ 15,791	\$ (266,389)	\$ 46,351

(1) Includes impairment charges of \$289.5 million during the three and nine months ended September 30, 2008 for goodwill and certain intangible assets

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

(In US\$ thousands)	Sales by Market Sector for the three month period ended September 30, 2008				
	Orthofix		Breg	Orthofix	
	Domestic	Blackstone		International	Total
Spine	\$ 35,340	\$ 25,338	\$ -	\$ 640	\$ 61,318
Orthopedics	11,725	-	-	22,099	33,824
Sports Medicine	-	-	22,377	1,323	23,700
Vascular	-	-	-	4,274	4,274
Other	-	-	-	6,185	6,185
Total	\$ 47,065	\$ 25,338	\$ 22,377	\$ 34,521	\$ 129,301

Table of Contents

(In US\$ thousands)	Sales by Market Sector for the three month period ended September 30, 2007				
	Orthofix Domestic	Blackstone	Breg	Orthofix International	Total
Spine	\$ 31,693	\$ 29,448	\$ -	\$ 168	\$ 61,309
Orthopedics	10,278			16,026	26,304
Sports Medicine	-	-	21,206	869	22,075
Vascular	-	-	-	4,718	4,718
Other	-	-	-	6,714	6,714
<b>Total</b>	<b>\$ 41,971</b>	<b>\$ 29,448</b>	<b>\$ 21,206</b>	<b>\$ 28,495</b>	<b>\$ 121,120</b>

(In US\$ thousands)	Sales by Market Sector for the nine month period ended September 30, 2008				
	Orthofix Domestic	Blackstone	Breg	Orthofix International	Total
Spine	\$ 104,143	\$ 81,093	\$ -	\$ 1,252	\$ 186,488
Orthopedics	34,254	-	-	62,665	96,919
Sports Medicine	-	-	66,341	3,871	70,212
Vascular	-	-	-	13,391	13,391
Other	-	-	-	20,362	20,362
<b>Total</b>	<b>\$ 138,397</b>	<b>\$ 81,093</b>	<b>\$ 66,341</b>	<b>\$ 101,541</b>	<b>\$ 387,372</b>

Table of ContentsSales by Market Sector  
for the nine month period ended September 30, 2007

(In US\$ thousands)	Orthofix Domestic	Blackstone	Breg	Orthofix International	Total
Spine	\$ 92,650	\$ 85,859	\$ -	\$ 421	\$ 178,930
Orthopedics	30,068	-	-	51,865	81,933
Sports Medicine	-	-	61,522	3,033	64,555
Vascular	-	-	-	15,217	15,217
Other	-	-	-	20,853	20,853
Total	\$ 122,718	\$ 85,859	\$ 61,522	\$ 91,389	\$ 361,488

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

## Identifiable Assets

(In US\$ thousands)	September 30, 2008	December 31, 2007
Domestic	\$ 112,807	\$ 118,178
Blackstone (1)	122,828	404,788
Breg	174,911	180,157
International	173,839	177,586
Group activities	10,198	20,063
Eliminations	(15,796)	(15,108)
Total	\$ 578,787	\$ 885,664

(1) Includes impairment charges related to goodwill and certain intangibles of \$289.5 million recorded as of September 30, 2008

## NOTE 14:

## INCOME TAXES

The difference between the reported benefit for income taxes and the tax benefit computed by applying the statutory rates applicable to each subsidiary of the Company is principally related to an impairment charge to goodwill for which the Company receives no tax benefit. 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 September 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. It is anticipated that the Company will release approximately \$1.0 million in tax reserves within the next twelve months for uncertain tax positions due to the expiration of certain statutes of limitations.

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. As of September 30, 2008, the Company had approximately \$0.5 million of accrued interest and penalties related to uncertain tax positions.

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 15: EARNINGS PER SHARE

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Weighted average common shares - basic	17,101,718	16,639,019	17,093,133	16,546,385
Effect of dilutive securities	-	250,284	-	378,699
Weighted average common shares – diluted	17,101,718	16,889,303	17,093,133	16,925,084

No adjustment has been made in the three and nine months ended September 30, 2008 for any common stock equivalents because their effects would be anti-dilutive. For the three and nine month periods ended September 30, 2008, potentially dilutive shares totaled 4,638 and 37,496, respectively.

For the three and nine month periods ended September 30, 2007, the Company did not include 172,218 and 145,218 options, respectively, in the diluted shares outstanding calculation because their inclusion would have been anti-dilutive or because their exercise price exceeded the average market price of the Company's common stock during the period.

## NOTE 16: DERIVATIVE INSTRUMENTS

In 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 September 30, 2008 was \$150.0 million. Under the Swap the Company 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 September 30, 2008 the interest rate on the debt related to the Swap was 8.2% (3.73% plus a margin of 4.50%). Our overall effective interest rate, including the impact of the Swap, as of September 30, 2008 on the senior secured debt was 8.2%. The instrument is designated as a cash flow hedge. The Company recognized an unrealized loss on the change in fair value of this swap arrangement of \$1.0 million and \$0.3 million, net of tax, for the three and nine months ended September 30, 2008, respectively.

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 September 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 \$1.0 million, net of tax, within other comprehensive income in the three months ended September 30, 2008. The Company recognized an unrealized gain on the change in fair value of this swap arrangement of \$0.2 million, net of tax, within other comprehensive

income in the nine months ended September 30, 2008.

NOTE 17:

FAIR VALUE MEASUREMENTS

18

---

Table of Contents

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 September 30, 2008	Level 1	Level 2	Level 3
Cash Equivalents	\$ 26	\$ 26	\$ -	\$ -
Derivative Financial Instruments(1)				
Cash Flow Hedges	\$ (2,176)	\$ -	\$ (2,176)	\$ -

(1) See Note 16, “Derivative Instruments”.

## NOTE 18:

## 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. 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 settlement agreement is not expected to have a

material impact on the Company's 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. The Company believes that the subpoena concerns the compensation of certain physician consultants and related matters. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the 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.

Table of Contents

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. On September 18, 2008, 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.

In connection with the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and United States Attorney's Office for the District of Massachusetts, the Company's legal counsel has been informed by representatives of the Department of Justice ("DOJ") that a qui tam lawsuit against Blackstone and another affiliate of the Company is pending in the U.S. District Court for the District of Massachusetts. The Company believes that the complaint alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants. The Company further understands that the seal in this qui tam lawsuit has been partially lifted for the purpose of allowing DOJ to disclose to the Company the existence of the qui tam lawsuit and discuss the allegations in the complaint, but that the qui tam lawsuit otherwise remains under seal as required by law. The Company intends to defend vigorously against this lawsuit. On September 18, 2008, we 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.

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 date of issuance of the subpoena. The Company believes that the subpoena concerns payments or gifts made by Blackstone to certain physicians. On September 18, 2008, 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.

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. On September 18, 2008, 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 Ohio Attorney General's Office, Health Care Fraud Section has issued a criminal subpoena, dated August 8, 2008, to Orthofix, Inc (the "Ohio AG Subpoena"). The Ohio AG Subpoena seeks documents for the period from January 1, 2000 through the date of issuance of the subpoena. The Company believes that the Ohio AG Subpoena arises from a government investigation that concerns the compensation of physician consultants and related matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to the Company or Blackstone resulting from this matter.

Blackstone is cooperating with the government's request in each of the subpoenas set forth above and is in the process of responding to the subpoenas. The Company is unable to predict what actions, if any, might be taken by the governmental authorities that have issued these subpoenas or what impact, if any, the outcome of these matters might have on the Company's consolidated financial positions, results of operations or cash flows.

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 it intends to defend vigorously against this lawsuit. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the 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.

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 were filed in the Circuit Court of White County, Arkansas. The Company has reached a settlement in one of these four civil lawsuits, and the court has entered an order of dismissal. The settlement agreement is not expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows. The Company believes that the Company and its subsidiaries have meritorious defenses to the claims alleged in the remaining three lawsuits and the Company and its subsidiaries intend to defend vigorously against these lawsuits if they are not settled. 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.

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 18, 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.

The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund and there can be no assurance that 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, or that their shares or stock options were improperly diluted by Blackstone. To date, the representative of the former shareholders of Blackstone has not objected to approximately \$1.5 million in such claims from the escrow fund, with certain claims remaining pending.

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

Table of Contents

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.

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.

Table of Contents

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

The following discussion and analysis addresses our liquidity, financial condition, and the results of our operations for the three and nine months ended September 30, 2008 compared to our results of operations for the three and nine months ended September 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 nine 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."

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 subsidiary, Orthofix Holdings, Inc.

Table of Contents

## 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 September 30,					
	2008		2007			
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Growth	
Domestic	\$ 47,065	36%	\$ 41,971	35%	12%	
Blackstone	25,338	20%	29,448	24%	(14)%	
Breg	22,377	17%	21,206	17%	6%	
International	34,521	27%	28,495	24%	21%	
Total	\$ 129,301	100%	\$ 121,120	100%	7%	

(In US\$ thousands)	Nine Months Ended September 30,					
	2008		2007			
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Growth	
Domestic	\$ 138,397	36%	\$ 122,718	34%	13%	
Blackstone	81,093	21%	85,859	24%	(6)%	
Breg	66,341	17%	61,522	17%	8%	
International	101,541	26%	91,389	25%	11%	
Total	\$ 387,372	100%	\$ 361,488	100%	7%	

Table of Contents

Market Sector:

(In US\$ thousands)	Three Months Ended September 30,				
	2008		2007		Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	
Spine	\$ 61,318	48%	\$ 61,309	51%	-%
Orthopedics	33,824	26%	26,304	22%	29%
Sports Medicine	23,700	18%	22,075	18%	7%
Vascular	4,274	3%	4,718	4%	(9)%
Other	6,185	5%	6,714	5%	(8)%
Total	\$ 129,301	100%	\$ 121,120	100%	7%

(In US\$ thousands)	Nine Months Ended September 30,				
	2008		2007		Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	
Spine	\$ 186,488	48%	\$ 178,930	49%	4%
Orthopedics	96,919	25%	81,933	23%	18%
Sports Medicine	70,212	18%	64,555	18%	9%
Vascular	13,391	4%	15,217	4%	(12)%
Other	20,362	5%	20,853	6%	(2)%
Total	\$ 387,372	100%	\$ 361,488	100%	7%

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		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
	(%)	(%)	(%)	(%)
Net sales	100	100	100	100
Cost of sales	37	25	30	26
Gross profit (1)	63	75	70	74
Operating expenses				
Sales and marketing	39	39	40	38
General and administrative	15	14	15	14
Research and development	5	5	5	5
Amortization of intangible assets	4	4	4	4
Impairment of goodwill and intangible assets	224	-	75	-
Total operating income (loss)	(224)	13	(69)	13
Net income (loss)	(184)	7	(59)	6

(1) Includes effect of obsolescence provision representing 8% and 3% points, respectively for the three and nine months ended September 30, 2008.

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

Net sales increased 7% to \$129.3 million for the third quarter of 2008 compared \$121.1 million for the same period last year. The impact of foreign currency increased sales by \$2.4 million during the third quarter of 2008 when compared to the third quarter of 2007.

#### Sales by Business Segment:

Net sales in Domestic increased to \$47.1 million in the third quarter of 2008 compared to \$42.0 million for the same period last year, an increase of 12%. Domestic's net sales represented 36% and 35% of total net sales during the third quarter of 2008 and 2007, respectively. The increase in Domestic's net sales was partially the result of a 12% increase in sales in our Spine market sector, which was mainly driven by the increase in sales of our Spinal-Stim® and Cervical-Stim® products. The increase in Domestic's net sales was also attributable to the 14% increase in our Orthopedic market sector which included an increase in sales of Physio-Stim® products as compared to the prior year period and an increase in sales of human cellular and tissue based products ("HCT/P products", often referred to as Biologic products) used in orthopedic applications for which there were no comparable sales in the prior year.

#### Domestic Sales by Market Sector:

(In US\$ thousands)	Net Sales for the		
	Three Months Ended September 30,		
	2008	2007	Growth
Spine	\$ 35,340	\$ 31,693	12%



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

Orthopedics	11,725	10,278	14%
Total	\$ 47,065	\$ 41,971	12%

Table of Contents

Net sales in Blackstone decreased \$4.1 million to \$25.3 million in the third quarter of 2008 compared to \$29.4 million for the same period last year, a decrease of 14%. Blackstone's net sales represented 20% and 24% of total net sales during the third quarter of 2008 and 2007, respectively. During the integration of Blackstone into our business we have experienced distributor terminations and government investigations, all of which negatively impacted our sales during the quarter. Sales may continue to be negatively impacted until the distributors are established in selling Blackstone products and scheduled new products are introduced. These decreases have been partially offset by the increase in sales attributable to our HCT/P products. All of Blackstone's sales are recorded in our Spine market sector.

Net sales in Breg increased \$1.2 million to \$ 22.4 million in the third quarter of 2008 compared to \$21.2 million for the same period last year, an increase of 6%. Breg's net sales represented 17% of total net sales during both third quarter of 2008 and 2007. The increase in Breg's net sales was primarily due to an 18% increase in sales of our cold therapy products when compared to the same period in the prior year which is due to the recent launch of our new Kodiak® cold therapy products. Further, sales of our Breg® bracing products increased 8% from the third quarter of 2007, primarily as a result of the sales of our Fusion XT™ and other new 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 21% to \$34.5 million in the third quarter of 2008 compared to \$28.5 million for the same period last year. International's net sales represented 27% and 24% of our total net sales in the third quarter of 2008 and 2007, respectively. The impact of foreign currency increased International net sales by 7% or \$2.1 million, during the third quarter of 2008 as compared to the third quarter of 2007. International net sales were positively impacted by an increase in sales of our Orthopedic products which increased by 38% as compared to the third quarter of 2007 primarily as a result of the sales of our internal fixation products including the eight-Plate Guided Growth System®, which increased 149% as well as a 29% increase in sales of our external fixation products. These increases were a result of higher than normal sales to a few international distributors that increased their inventory levels to accommodate higher demand for certain products. Further, sales of Breg products within International included in the Sports Medicine sector, increased 52% when compared to third quarter of 2007. Offsetting these increases, International sales in our Vascular sector, which consists of the A-V Impulse System®, decreased \$0.4 million or 9% from the third quarter of 2007. Sales are expected to return to higher historic levels in the remainder of 2008. Sales of distributed products, which includes the Laryngeal Mask, also decreased approximately \$0.5 million or 8% from the third quarter of 2007.

## International Sales by Market Sector:

(In US\$ thousands)	Net Sales for the Three Months Ended September 30,			Growth
	2008	2007		
Spine	\$ 640	\$ 168		281%
Orthopedics	22,099	16,026		38%
Sports Medicine	1,323	869		52%
Vascular	4,274	4,718		(9)%
Other	6,185	6,714		(8)%
<b>Total</b>	<b>\$ 34,521</b>	<b>\$ 28,495</b>		<b>21%</b>

Sales by Market Sector:

Sales of our Spine products remained constant at approximately \$61.3 million in the third quarters of both 2008 and 2007. Sales of our Cervical- Stim® and Spinal-Stim® products increased 16% and 9%, respectively from the third quarter of 2007 compared to the third quarter of 2008. These increases were offset by a 13% decrease in sales of Blackstone products from the third quarter of 2007 as a result of substantial turnover of distributors in Blackstone as previously discussed. Spine product sales were 48% and 51% of our total net sales in the third quarters of both 2008 and 2007, respectively.

Table of Contents

Sales of our Orthopedic products increased 29% to \$33.8 million in the third quarter of 2008 compared to \$26.3 million for the same period last year. The increase of \$7.5 million can be primarily attributed to a 91% increase in sales of our internal fixation devices including the eight-Plate Guided Growth System® as well as a 24% increase in sales of our external fixation devices. Also contributing to the increase was an 8% increase in sales of our Physio-Stim® products as compared to the prior year period and an increase in sales of HCT/P products used in orthopedic applications for which there were no comparable sales in the prior year. Orthopedic product sales were 26% and 22% of our total net sales in the third quarter of 2008 and 2007, respectively.

Sales of our Sports Medicine products increased 7% to \$23.7 million in the third quarter of 2008 compared to \$22.1 million for the same period last year. As discussed above, the increase of \$1.6 million is primarily due to sales of our Breg® cold therapy and bracing products, offset by a decrease in our pain therapy products, which is principally attributable to the sale of operations relating to our Pain Care® line in March 2008. Sports Medicine product sales were 18% of our total net sales in both the third quarter of 2008 and the third quarter of 2007.

Sales of our Vascular products, which consist of our A-V Impulse System®, decreased 9% to \$4.3 million in the third quarter of 2008 compared to \$4.7 million for the same period last year. Vascular product sales were 3% and 4% of our total net sales in the third 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, decreased 8% to \$6.2 million in the third quarter of 2008 when compared to \$6.7 million for the same period last year. Other product sales were 5% of our total net sales in both third quarter of 2008 and 2007.

Gross Profit - Our gross profit decreased 10% to \$81.3 million in the third quarter of 2008, compared to \$90.4 million for the same period last year. In the quarter ended September 30, 2008, due to reduced projections in revenue, distributor terminations, new products, and the replacement of one of our products with a successor product, the Company changed its estimates regarding the inventory allowance at Blackstone, primarily based on estimated net realizable value using assumptions about future demand and market conditions. The change in estimate resulted in an increase in the reserve for obsolescence of approximately \$10.9 million. In addition, the Company recorded approximately \$0.6 million of expense related to Blackstone instrumentation equipment, also as a result of the replacement of one of our products with a successor product. Gross profit as a percent of net sales in the third quarter of 2008 was 62.9% compared to 74.6% in the third quarter of 2007. Gross profit, excluding the additional reserve recorded at Blackstone was 71.8% in the quarter ended September 30, 2008. Gross profit was also negatively impacted principally by changes in product and geographic mix.

Sales and Marketing Expense - Sales and marketing expense, which includes commissions, royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$3.2 million, or 7%, to \$50.2 million in the third quarter of 2008 compared to \$47.1 million in the third quarter of 2007. Included in sales and marketing expense in the third quarter of 2008 was approximately \$0.7 million of corporate reorganization expenses. As a percent of sales, sales and marketing expense was 38.8% in the third quarters of both 2008 and 2007.

General and Administrative Expense - General and administrative expense increased \$2.4 million, or 14%, in the third quarter of 2008 to \$19.3 million compared to \$16.9 million in the third quarter of 2007. This increase is primarily a result of approximately \$1.7 million of corporate reorganization expenses. General and administrative expense as a percent of sales was 14.9% in the third quarter of 2008 compared to 14.0% for the same period last year.

Table of Contents

Research and Development Expense - Research and development expense increased \$0.5 million in the third quarter of 2008 to \$6.4 million compared to \$6.0 million for the same period last year. This increase is primarily a result of approximately \$0.5 million of expenses incurred related to the collaborative arrangement with Musculoskeletal Transplant Foundation (“MTF”). As a percent of sales, research and development expense was 5.0% in the third quarter of 2008 compared to 4.9% for the same period last year. For the remainder of 2008, research and development expenses are expected to increase as a result of the agreements we entered into with MTF and Intelligent Implant Systems, LLC (“IIS”). We expect to incur up to \$3.5 million of expense related to these agreements in 2008; see Liquidity and Capital Resources for further detail.

Amortization of Intangible Assets – Amortization of intangible assets increased \$0.7 million, or 14%, in the third quarter of 2008 to \$5.3 million compared to \$4.7 million for the same period last year. 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.

Impairment of Goodwill and Certain Intangible Assets – In the third quarter of 2008, we incurred \$289.5 million of expense related to the impairment of goodwill and certain intangible assets. In accordance with SFAS No. 142, “Goodwill and Other Intangible Assets,” we performed an impairment analysis of indefinite-lived intangibles. We determined that the Blackstone trademark, an indefinite-lived intangible asset, was impaired by \$57.0 million. As part of our debt refinancing completed in September 2008, five year projections were prepared for Blackstone. Due to the recent trend of decreasing revenues at Blackstone, we evaluated the fair value of goodwill at Blackstone. The fair value was estimated using the expected present value of future cash flows. We determined that the carrying amount of goodwill related to Blackstone exceeded its implied fair value, and recognized a goodwill impairment loss of \$126.9 million. In addition, in accordance with SFAS No. 144 “Accounting for the Impairment or Disposal of Long-Lived Assets” we determined that a Triggering Event had occurred with respect to the definite-lived intangible assets at Blackstone. We compared the expected cash flows to be generated by the definite lived intangible on an undiscounted basis to the carrying value of the intangible asset. We determined the carrying value exceed the undiscounted cash flow and impaired the distribution network and technologies at Blackstone to the fair value which resulted in a impairment charge of \$105.7 million. There is no comparable cost in the third quarter of 2007.

Interest Income (Expense), net – Interest expense, net was \$4.2 million for the third quarter of 2008 compared to \$5.7 million for the same period last year. Interest expense for the third 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.

Loss on Refinancing of Senior Secured Term Loan – In the third quarter of 2008, we incurred \$5.7 million of expense related to the refinancing of the senior secured term loan which was originally used to finance the Blackstone acquisition. This included a \$3.7 million non-cash write-off of previously capitalized debt placement costs and \$2.0 million of fees associated with the amendment. We anticipated that we would not remain in compliance with certain financial covenants included in the senior secured credit facility and consequently negotiated an amendment of our debt covenants, among other things, with our lenders effective September 29, 2008.

Table of Contents

Other, net – Other, net was expense of \$3.8 million for the third quarter of 2008 compared to income of \$0.5 million for the same period last year. The decrease can be mainly attributed to the effect of foreign exchange. During the third quarter, notably in September, we recorded foreign exchange losses of \$2.2 million principally as a result of a rapid strengthening of the US Dollar against various foreign currencies including the Euro, Pound, Peso and Brazilian Real. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the US Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies. In October, the US Dollar has continued to strengthen relative to the currencies noted above which could result in further foreign exchange losses in our fourth quarter.

Income Tax Expense (Benefit) – Our estimated worldwide effective tax rates were a benefit of 21.8% and an expense of 24.6% during the third quarters of 2008 and 2007, respectively. The effective tax benefit for the third quarter included an unfavorable discrete item resulting from the impairment of goodwill for which we receive no tax benefit. The effective tax rate for the third quarter of 2007 included a favorable discrete item which was a tax credit for research and development expense related to 2003. Excluding these discrete items in the third quarters of 2008 and 2007, our effective tax rate was a 38.8% benefit and a 26.7% tax rate, respectively. The increase in the effective tax rate excluding discrete items, compared to the effective tax rate excluding discrete items in the third quarter of 2007, was due to the termination of tax planning associated with the acquisition of Breg and lower pre-tax income for which deductions could not be realized.

Net Income (Loss) – Net loss for the third quarter of 2008 was \$(237.3) million, or \$(13.87) per basic and diluted share, compared to net income of \$8.0 million, or \$0.48 per basic and diluted share, for the same period last year. The weighted average number of basic common shares outstanding was 17,101,718 and 16,639,019 during the third quarters of 2008 and 2007, respectively. The weighted average number of diluted common shares outstanding was 17,101,718 and 16,889,303 during the third quarters of 2008 and 2007, respectively.

Nine Months Ended September 30, 2008 Compared to Nine Months Ended September 30, 2007

Net sales increased 7% to \$387.4 million for the nine months ended September 30, 2008 compared to \$361.5 million for the same period last year. The impact of foreign currency increased sales by \$7.6 million during the nine months ended September 30, 2008 as compared to the same period of 2007.

Sales by Business Segment:

Net sales in Domestic increased to \$138.4 million for the nine months ended September 30, 2008 compared to \$122.7 million for the same period last year, an increase of 13%. Domestic's net sales represented 36% and 34% of total net sales for the nine months ended September 30, 2008 and 2007, respectively. The increase in Domestic's net sales was partially the result of a 12% increase in sales in our Spine market sector, which was mainly driven by the increase in sales of our Spinal-Stim® and Cervical-Stim® products. The increase in Domestic's net sales was also attributable to an increase in our Orthopedic market sector which included an increase in sales of Physio-Stim® products as compared to the prior year period and an increase in sales of human cellular and tissue based products ("HCT/P products", often referred to as Biologic products) used in orthopedic applications for which there were no comparable sales in the prior year. These increases were partially offset by a 5% decrease in sales of external fixation products compared to the same period last year.

Table of Contents

## Domestic Sales by Market Sector:

(In US\$ thousands)	Net Sales for the Nine Months Ended September 30,		Growth
	2008	2007	
Spine	\$ 104,143	\$ 92,650	12%
Orthopedics	34,254	30,068	14%
Total	\$ 138,397	\$ 122,718	13%

Net sales in Blackstone decreased 6% to \$81.1 million for the nine months ended September 30, 2008 compared to \$85.9 million for the same period last year. Blackstone's net sales represented 21% and 24% of total net sales during the nine months ended September 30, 2008 and 2007, respectively. During the integration of Blackstone into our business we have experienced distributor terminations, government investigations and the replacement of one of our products with a successor product, all of which negatively impacted our sales during the nine months ended September 30, 2008. Our sales may continue to be negatively impacted by this turnover until the distributors are established in selling Blackstone products and new products are introduced. These decreases in sales have been partially offset by the increase in sales of our HCT/P products. All of Blackstone's sales are recorded in our Spine market sector.

Net sales in Breg increased \$4.8 million to \$66.3 million for the nine months ended September 30, 2008 compared to \$61.5 million for the same period last year, an increase of 8%. Breg's net sales represented 17% of total net sales during both nine months ended September 30, 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 12% compared to the nine months ended September 30, 2007, caused primarily by increased sales of our Fusion XT™ and other new products. Further, sales of our cold therapy products increased 16% when compared to the same period last year which is due to the recent launch of our new Kodiak® cold therapy products. These increases were partially offset by a decrease in sales of our pain therapy products as a result of the sale of operations related to our Pain Care® line of ambulatory infusion pumps during March 2008. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International increased 11% to \$101.5 million for the nine months ended September 2008 compared to \$91.4 million for the same period last year. International's net sales represented 26% and 25% of our total net sales for the nine months ended September 30, 2008 and 2007, respectively. The impact of foreign currency increased International net sales by 8% or \$7.1 million, during the nine months ended September 30, 2008 as compared to the same period last year. The sales of our Orthopedic products increased 21% when compared to the nine months ended September 30, 2007 primarily as a result of increased sales of our internal fixation products including the eight-Plate Guided Growth System®, which increased 75% as well as a 12% increase in sales of our external fixation products. Further, sales of Breg products within International, included in the Sports Medicine sector increased 28% when compared to the nine months ended September 30, 2007. International sales in our Vascular sector, which consists of the A-V Impulse System®, decreased \$1.8 million or 12% compared to the nine months ended September 30, 2007. Sales are expected to return to higher historic levels in the remainder of 2008. Sales of distributed products, which include the Laryngeal Mask, decreased approximately 2%.

Table of Contents

## International Sales by Market Sector:

## Sales by Market Sector:

(In US\$ thousands)	Net Sales for the		
	Nine Months Ended September 30,		
	2008	2007	Growth
Spine	\$ 1,252	\$ 421	197%
Orthopedics	62,665	51,865	21%
Sports Medicine	3,871	3,033	28%
Vascular	13,391	15,217	(12)%
Other	20,362	20,853	(2)%
<b>Total</b>	<b>\$ 101,541</b>	<b>\$ 91,389</b>	<b>11%</b>

Sales of our Spine products increased 4% to \$186.5 million for the nine months ended September 30, 2008 compared to \$178.9 million for the same period last year. The increase of \$7.6 million is primarily due to a 13% increase in sales of spinal stimulation products in the United States. Spine product sales were 48% and 49% of our total net sales in the nine months ended September 30, 2008 and 2007, respectively.

Sales of our Orthopedic products increased 18% to \$96.9 million for the nine months ended September 2008 compared to \$81.9 million for the same period last year. The increase of \$15.0 million can be mainly attributed to a 51% increase in sales of our internal fixation devices including the eight-Plate Guided Growth System® as well as an 8% increase in sales of our external fixation devices. Also attributing to the increase in sales was an 11% increase in sales of our Physio-Stim® products as compared to the prior year period and an increase in sales of HCT/P products used in orthopedic applications for which there were no comparable sales in the prior year. Orthopedic product sales were 25% and 23% of our total net sales for the nine months ended September 30, 2008 and 2007, respectively.

Sales of our Sports Medicine products increased 9% to \$70.2 million for the nine months ended September 30, 2008 compared to \$64.6 million for the same period last year. As discussed above, the increase of \$5.7 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 for both nine months ended September 30, 2008 and 2007.

Sales of our Vascular products, which consist of our A-V Impulse System®, decreased 12% to \$13.4 million for the nine months ended September 30, 2008 compared to \$15.2 million for the same period last year. Sales are expected to return to higher historic levels in the remainder of 2008. Vascular product sales were 4% of our total net sales for both nine months ended September 30, 2008 and 2007.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our Woman's Care line, decreased 2% to \$20.4 million for the nine months ended September 30, 2008 compared to \$20.9 million for the same period last year. Other product sales were 5% and 6% of our total net sales for the nine months ended September 30, 2008 and 2007, respectively.



Table of Contents

**Gross Profit** - Our gross profit increased 1% to \$270.1 million for the nine months ended September 30, 2008, compared to \$266.9 million for the same period last year. In the nine months ended September 30, 2008, due to reduced projections in revenue, distributor terminations, new products, and the replacement of one of our products with a successor product, the Company changed its estimates regarding the inventory allowance at Blackstone, primarily based on estimated net realizable value using assumptions about future demand and market conditions. In addition, the Company recorded approximately \$0.6 million of expense related to Blackstone instrumentation equipment, also as a result of the replacement of one of our products with a successor product. During the nine months ended September 30, 2007, we recorded a charge of \$2.7 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 nine months ended September 30, 2008. Gross profit as a percent of net sales for the nine months ended September 30, 2008 and 2007 was 69.7% and 73.8%, respectively. Gross profit, excluding the additional reserve recorded at Blackstone was 72.7% in the quarter ended September 30, 2008. The lower margin is principally the result of changes in product and geographic mix.

**Sales and Marketing Expense** - Sales and marketing expense, which includes commissions, royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$14.7 million, or 11%, to \$153.7 million for the nine months ended September 30, 2008 compared to \$138.9 million for the same period last year. This increase is attributed to increased expense in order to support increased sales activity, including higher commissions on higher sales as well as approximately \$0.7 million of expense related to corporate reorganizations. 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. As a percent of sales, sales and marketing expense was 39.7% and 38.4% for the nine months ended September 30, 2008 and 2007, respectively.

**General and Administrative Expense** - General and administrative expense increased \$10.6 million, or 21%, for the nine months ended September 30, 2008 to \$60.3 million compared to \$49.6 million for the same period last year. The increase was primarily attributable to a charge of \$2.8 million recorded during the nine months ended September 30, 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. We also incurred approximately \$1.7 million of expense in the third quarter of 2008 related to corporate reorganizations. General and administrative expense as a percent of sales was 15.5% and 13.7% for the nine months ended September 30, 2008 and 2007, respectively.

**Research and Development Expense** - Research and development expense increased \$1.1 million to \$19.4 million for the nine months ended September 30, 2008 compared to \$18.3 million for the same period last year. In the nine months ended September 30, 2008, we incurred \$0.5 million in expenses as a result of the agreement we entered into with MTF. For the remainder of 2008, research and development expenses are expected to increase as a result of the agreements we entered into with MTF and IIS. We expect to incur up to \$3.5 million of expense related to these agreements in 2008; see Liquidity and Capital Resources for further detail. As a percent of sales, research and development expense was 5.0% for both the nine months ended September 30, 2008 and the nine months ended September 30, 2007.

**Amortization of Intangible Assets** - Amortization of intangible assets increased approximately \$1.5 million, or 11%, for the first nine months ended September 30, 2008 to \$15.2 million compared to \$13.7 million for the same period last year. 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.

**Impairment of Goodwill and Certain Intangible Assets** - In the nine months ended September 30, 2008, we incurred \$289.5 million of expense related to the impairment of goodwill and certain intangible assets. In accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," we performed an impairment analysis of indefinite-lived

intangibles. We determined that the Blackstone trademark, an indefinite-lived intangible asset, was impaired by \$57.0 million. As part of our debt refinancing completed in September 2008, five year projections were prepared for Blackstone. Due to the recent trend of decreasing revenues at Blackstone, we evaluated the fair value of goodwill at Blackstone. The fair value of Blackstone was estimated using the expected present value of future cash flows. We determined that the carrying amount of goodwill related to Blackstone exceeded its implied fair value, and recognized a goodwill impairment loss of \$126.9 million. In addition, in accordance with SFAS No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" we determined that a Triggering Event had occurred with respect to the definite-lived intangible assets at Blackstone. We compared the expected cash flows to be generated by the definite lived intangible on an undiscounted basis to the carrying value of the intangible asset. We determined the carrying value exceed the undiscounted cash flow and impaired the distribution network and technologies at Blackstone to the fair value which resulted in a impairment charge of \$105.7 million. There is no comparable cost in the first nine months of 2007.

Table of Contents

Gain on Sale of Pain Care® Operations – Gain on sale of Pain Care® operations was \$1.6 million for the nine months ended September 30, 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 same period of 2007.

Interest Income (Expense), net – Interest expense, net was \$13.7 million for the nine months ended September 30, 2008 compared to \$17.2 million for the same period last year. Interest expense for the nine months ended September 30, 2008 and 2007 included interest expense of \$11.5 million and \$16.8 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.

Loss on Refinancing of Senior Secured Term Loan – In the nine months ended September 30, 2008, we incurred \$5.7 million of expense related to the refinancing of the senior secured term loan used to finance the Blackstone acquisition. This included a \$3.7 million non-cash write-off of previously capitalized debt placement costs and \$2.0 million of fees associated with the amendment. We anticipated that we would not remain in compliance with certain financial covenants included in the senior secured credit facility and, consequently negotiated an amendment of our financial covenants, among other things, with our lenders effective September 29, 2008.

Other, net – Other, net was expense of \$2.7 million for the nine months ended September 30, 2008 compared to income of \$0.2 million for the same period last year. The decrease can be mainly attributed to the effect of foreign exchange. During the third quarter, notably in September, we recorded foreign exchange losses of \$2.2 million principally as a result of a rapid strengthening of the US Dollar against various foreign currencies including the Euro, Pound, Peso and Brazilian Real. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the US Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies. In October, the US Dollar has continued to strengthen relative to the currencies noted above which could result in further foreign exchange losses in our fourth quarter.

Income Tax Expense (Benefit) – Our estimated worldwide effective tax rates were a benefit of 21.0% and expense of 26.9% during the nine months ended September 30, 2008 and 2007, respectively. The effective tax benefit for the nine months ended September 2008 included unfavorable discrete items resulting from the impairment of goodwill for which we receive no tax benefit and the sale of operations related to our Pain Care® operations. Excluding these discrete items, our effective tax benefit rate was 39.5%. The effective tax rate for the nine months ended September 30, 2007 included a tax credit for research and development expense related to 2003. Without discrete items our estimated worldwide effective tax rate for the nine months ended September 30, 2007 was 27.5% due to the positive effects of our European restructuring, research and development tax credits, tax planning associated with the acquisition of Breg, non-deductible foreign losses, and an increase in the domestic production deduction which were partially offset by the generation of net operating losses in various jurisdictions that were not benefitted.

Net Income (Loss) – Net loss for the nine months ended September 30, 2008 was \$(227.8) million, or \$(13.33) per basic and diluted share, compared to net income of \$21.5 million, or \$1.30 per basic share and \$1.27 per diluted share, for the same period last year. The weighted average number of basic common shares outstanding was 17,093,133 and 16,546,385 during the nine months ended September 30, 2008 and 2007, respectively. The weighted average number of diluted common shares outstanding was 17,093,133 and 16,925,084 during the nine months ended September 30, 2008 and 2007, respectively.

Table of Contents

## Liquidity and Capital Resources

Cash and cash equivalents at September 30, 2008 were \$27.0 million, of which \$16.8 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 was \$2.4 million for the nine months ended September 30, 2008 compared to \$13.8 million for the same period last year. Net cash provided by operating activities is comprised of net income (loss), non-cash items (including share-based compensation, inventory provisions and non-cash purchase accounting items from the Blackstone and Breg acquisitions) and changes in working capital, including changes in restricted cash. Net income (loss) decreased \$249.3 million to a net loss of \$227.8 million for the nine months ended September 30, 2008 from net income of \$21.5 million for the comparable period in the prior year. Non-cash items for the nine months ended September 30, 2008 increased \$235.7 million compared to the same period last year primarily as a result of the impairment of goodwill and intangible assets of \$289.5 million, the change in estimate for inventory provisions of \$10.9 million and the loss on refinancing of senior secured term loan of \$3.7 million which was partially offset by the change in deferred taxes of \$76.9 million, primarily attributable to the intangibles impairment, and the \$1.6 million gain on the sale of the operations related to the Breg Pain Care® line. Working capital accounts consumed \$36.3 million of cash in the nine months ended September 30, 2008 compared to \$38.6 million for the same period last year. 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. Specifically, increases in inventory at Blackstone were approximately \$18.3 million which included significant purchases of Trinity® bone growth matrix due, in part, to the pending expiration of a related supply agreement. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 82 days at September 30, 2008 compared to 90 days at September 30, 2007 and inventory turns of 2.0 times at September 30, 2008 compared to 1.4 times at September 30, 2007. The higher inventory turns and resultant lower inventory balances reflect an additional reserve recorded in the three months ended September 30, 2008 for inventory obsolescence at Blackstone. Also included in the uses of working capital were \$6.0 million in payments related to strategic initiatives with MTF and IIS, \$4.7 million in payments related to the potential divestiture of certain orthopedic fixation assets and \$5.2 million in costs related to matters occurring at Blackstone prior to the acquisition and for which we are seeking reimbursement from the applicable escrow fund.

Net cash used in investing activities was \$9.6 million during the nine months ended September 30, 2008 compared to \$25.9 million used in investing activities during the same period last year. During the nine months ended September 30, 2008, we sold the operations of our Pain Care® line of ambulatory infusion pumps for net proceeds of \$6.0 million. During the nine months ended September 30, 2008, we also sold a portion of our ownership in OPED AG, a German based bracing company, for net proceeds of \$0.8 million. In the nine months ended September 30, 2008, we invested \$15.8 million in capital expenditures, of which \$7.6 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 nine months ended September 30, 2007, we invested \$23.8 million in capital expenditures of which \$13.4 million were related to Blackstone. In the nine months ended September 30, 2007, we also invested \$2.1 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 \$7.1 million for the nine months ended September 30, 2008 compared to \$9.3 million provided by financing activities the same period last year. During the nine months ended September 30, 2008, we repaid approximately \$6.2 million against the principal on our senior secured term loan and repaid \$2.4 million related to borrowings by our Italian subsidiary. In addition, we received proceeds of \$1.7 million from the issuance of 51,052 shares of our common stock upon the exercise of stock options and shares issued pursuant to the employee stock purchase plan. During the nine months ended September 30, 2007, we repaid \$6.5 million against the

principal on our senior secured term loan and borrowed \$7.9 million to support working capital in our Italian subsidiary. In addition, we received proceeds of \$6.8 million from the issuance of 230,894 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. Certain terms of the senior secured credit facility were amended September 29, 2008. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million, the proceeds of which, together with cash balances were used for payment of the purchase price of Blackstone; and (2) a six-year revolving credit facility of \$45.0 million. As of September 30, 2008 we had no amounts outstanding under the revolving credit facility and \$291.5 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 4.50%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. In June 2008, we entered into a three year fully amortizable interest rate swap agreement (the “Swap”) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of September 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 September 30, 2008 the interest rate on the debt related to the Swap was 8.2% (3.73% plus a margin of 4.50%). Our overall effective interest rate, including the impact of the Swap, as of September 30, 2008 on our senior secured debt was 8.2%.

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 we are in compliance with these financial covenants as measured at September 30, 2008.

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 September 30, 2008, we had outstanding borrowings of \$6.2 million and unused available lines of credit of approximately 2.9 million Euro (\$4.1 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

We 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 if capacity under the financial covenants is available.

On July 24, 2008, we entered into an agreement with Musculoskeletal Transplant Foundation (“MTF”) to collaborate on the development and commercialization of a new stem cell-based bone growth biologic matrix. Under the terms of the agreement, we 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. We account for this collaborative arrangements under guidance included in Emerging Issues Task Force Issue No. 07-1 “Accounting for Collaborative

Arrangements.” We currently plan for the new matrix to be launched in the U.S. during 2009. Approximately \$0.5 million of expenses incurred under the terms of the agreement are included in research and development expense in the three and nine months ended September 30, 2008. 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.

Table of Contents

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

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 September 30, 2008, we had a currency swap in place to minimize foreign currency exchange risk related to a 43.0 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 September 30, 2008 to minimize interest rate risk related to our LIBOR-based borrowings.

As of September 30, 2008, we had \$291.5 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 4.50%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. In June 2008, we entered into a Swap with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of September 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 September 30, 2008 the interest rate on the debt related to the Swap was 8.2% (3.73% plus a margin of 4.50%). Our overall effective interest rate, including the impact of the Swap, as of September 30, 2008 on our senior secured debt was 8.2%. Based on the balance outstanding under the senior secured term loan combined with the Swap as of September 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 September 30, 2008, we had an uncovered intercompany receivable denominated in Euro for approximately \$16.6 million. We recorded a foreign currency loss during the nine months ended September 30, 2008 of \$0.6 million which resulted from the weakening of the Euro against the U.S. dollar during the period.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the nine months ended September 30, 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 September 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. 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. 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. 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

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. On September 18, 2008, 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.

In connection with the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and United States Attorney's Office for the District of Massachusetts, our legal counsel has been informed by representatives of the Department of Justice (“DOJ”) that a qui tam lawsuit against Blackstone and another affiliate of the Company is pending in the U.S. District Court for the District of Massachusetts. We believe that the complaint alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants. We further understand that the seal in this qui tam lawsuit has been partially lifted for the purpose of allowing DOJ to disclose to us the existence of the qui tam lawsuit and discuss the allegations in the complaint, but that the qui tam lawsuit otherwise remains under seal as required by law. We intend

to defend vigorously against this lawsuit. On September 18, 2008, 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.

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 date of issuance of the subpoena. We believe that the subpoena concerns payments or gifts made by Blackstone to certain physicians. On September 18, 2008, 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.

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. On September 18, 2008, 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.

The Ohio Attorney General’s Office, Health Care Fraud Section has issued a criminal subpoena, dated August 8, 2008, to Orthofix, Inc (the “Ohio AG Subpoena”). The Ohio AG Subpoena seeks documents for the period from January 1, 2000 through the date of issuance of the subpoena. We believe that the Ohio AG Subpoena arises from a government investigation that concerns the compensation of physician consultants and related matters. On September 18, 2008, we submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from this matter.

Blackstone is cooperating with the government’s request in each of the subpoenas set forth above and is in the process of responding to the subpoenas. The Company is unable to predict what actions, if any, might be taken by the governmental authorities that have issued these subpoenas or what impact, if any, the outcome of these matters might have on the Company’s consolidated financial position, results of operations or cash flows.

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.

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 were filed in the Circuit Court of White County, Arkansas. We have reached a settlement in one of these four civil lawsuits, and the court has entered an order of dismissal. The settlement agreement is not expected to have a material impact on our consolidated financial position, results of operations or cash flows. We believe that we have meritorious defenses to the claims alleged in the remaining three lawsuits, and we intend to defend vigorously against these lawsuits if they are not settled. 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.

40

---

Table of Contents

We are unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to us from the escrow fund and there can be no assurance that losses to us from these matters will not exceed the amount of the escrow account.

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, or that their shares or stock options were improperly diluted by Blackstone. To date, the representative of the former shareholders of Blackstone has not objected to approximately \$1.5 million in such claims from the escrow fund, with certain claims remaining pending.

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

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

Item 1A. Risk Factors

The following risk factor should be read in conjunction with the other risk factors discussed in Part 1, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (the "Form 10-K), there have been no material changes to our risk factors from the factors discussed in our Form 10-K.

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 \$291.5 million was outstanding at September 30, 2008, and (2) a six-year revolving credit facility of \$45.0 million upon which we had not drawn as of September 30, 2008. On September 29, 2008, we entered into an amendment to the credit agreement.

The credit agreement, as amended, 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 September 30, 2008. The Company further believes that it should be able to meet these financial covenants in future fiscal quarters, however, there can be no assurance that it will be able to do so, and failure to do so could result in an event of default under the credit agreement, which could have a material adverse effect on our financial position.

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, as amended, 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.

The conditions of the U.S. and international capital and credit markets may adversely affect our ability to draw on our current revolving credit facility or obtain future short-term or long-term lending.



Table of Contents

Global market and economic conditions have been, and continue to be, disrupted and volatile, and in recent months the volatility has reached unprecedented levels. In particular, the cost and availability of funding for many companies has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. These forces reached unprecedented levels in September and October 2008, resulting in the bankruptcy or acquisition of, or government assistance to, several major domestic and international financial institutions. These events have significantly diminished overall confidence in the financial and credit markets. There can be no assurances that recent government responses to the disruptions in the financial and credit markets will restore consumer confidence, stabilize the markets or increase liquidity and the availability of credit.

We continue to maintain a six-year revolving credit facility of \$45.0 million upon which we have not drawn as of September 30, 2008. However, to the extent our business requires us to access the credit markets in the future and we are not able to do so, including in the event that lenders cease to lend to us, or cease to be capable of lending, for any reason, we could experience a material and adverse impact on our financial condition and ability to borrow additional funds. This might impair our ability to obtain sufficient funds for working capital, capital expenditures, acquisitions, research and development and other corporate purposes.

The conditions of the U.S. and international capital and credit markets may adversely affect our interest expense under our existing credit facility.

Our senior bank facility provides for a seven-year amortizing term loan facility of \$330.0 million for which \$291.5 was outstanding as of September 30, 2008. 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 4.50%. In June 2008, we entered into a three year fully amortizable interest rate swap agreement (the “Swap”) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of September 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 September 30, 2008 the interest rate on the debt related to the Swap was 8.2% (3.73% plus a margin of 4.50%). Our overall effective interest rate, including the impact of the Swap, as of September 30, 2008 on our senior secured debt was 8.2%.

In recent months, LIBOR rates have experienced unprecedented short-term volatility due to disruptions occurring in global financial and credit markets. During this period, LIBOR rates have experienced substantial short-term increases. As described above, although the Swap reduces the impact of these increases on us, increases in LIBOR rates increase the interest expense that we incur under our term loan. (See Item 3, Quantitative and Qualitative Disclosures about Market Risk in this Form 10-Q.) Further, in the event that our counterparties under the Swap were to cease to be able to satisfy their obligations under the Swap for any reason, our interest expense could be further increased.

Table of Contents

Adverse changes in general economic or credit market conditions in any of the major countries in which we do business could adversely impact our operating results.

The direction and strength of the U.S. and global economy has recently been increasingly uncertain due to a turndown in the economy and difficulties in the credit markets. If economic growth in the United States and other countries is slowed significantly, or if the credit markets continue to be difficult to access, our distributors, suppliers and other business partners could experience significant disruptions to their businesses and operations which, in turn, could negatively impact our business operations and financial performance.

## Item 6. Exhibits

## (a) Exhibits

Exhibit Number	Description
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
3.2	Articles of Association of the Company as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
10.1	Orthofix International N.V. Amended and Restated Stock Purchase Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
10.2	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).

Table of Contents

- 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 Acquisition Agreement dated as of November 20, 2003, among Orthofix International N.V., Trevor Acquisition, Inc., Breg, Inc. and Bradley R. Mason, as shareholders' representative (filed as an exhibit to the Company's current report on Form 8-K filed January 8, 2004 and incorporated herein by reference).
- 10.12 Amended and Restated Voting and Subscription Agreement dated as of December 22, 2003, among Orthofix International N.V. and the significant shareholders of Breg, Inc. identified on the signature pages thereto (filed as an exhibit to the Company's current report on Form 8-K filed on January 8, 2004 and incorporated herein by reference).
- 10.13 Amendment to Employment Agreement dated December 29, 2005 between Orthofix Inc. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed December 30, 2005 and incorporated herein by reference).
- 10.14 Form of Indemnity Agreement (filed as an exhibit to the Company's annual report on Form 10-K filed December 31, 2005 and incorporated herein by reference).
- 10.15 Settlement Agreement dated February 23, 2006, between Intavent Orthofix Limited, a wholly-owned subsidiary of Orthofix International N.V. and Galvin Mould (filed as an exhibit to the Company's annual report on Form 8-K filed on April 17, 2006 and incorporated herein by reference).
- 10.16 Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and 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).
- 10.17 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).
- 10.18 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).

10.19 Credit Agreement, dated as of September 22, 2006, among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, the several banks and other financial institutions as may from time to time become parties thereunder, and Wachovia Bank, National Association (filed as an exhibit to the Company's current report on Form 8-K filed September 27, 2006 and incorporated herein by reference).

Table of Contents

- 10.20 First Amendment to Credit Agreement, dated September 29, 2008, by and among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, and Wachovia Bank, National Association, as administrative agent on behalf of the Lenders under the Credit Agreement (filed as an exhibit to the Company's current report on Form 8-K filed September 29, 2008 and incorporated herein by reference).
- 10.21 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).
- 10.22 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).
- 10.23 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).
- 10.24 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).
- 10.25 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).
- 10.26 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).
- 10.27 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).

Table of Contents

- 10.28 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).
- 10.29 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).
- 10.30 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).
- 10.31 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).
- 10.32 Employment Agreement between Orthofix Inc. and Denise E. Pedulla dated as of June 9, 2008 (filed as an exhibit to the company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
- 10.33 Form of Inducement Grant Nonqualified Stock Option Agreement between Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the current report on Form 8-K of Orthofix International N.V dated September 10, 2008 and incorporated herein by reference).
- 10.34 Employment Agreement between Orthofix Inc. and Robert S. Vaters effective September 7, 2008 (filed as an exhibit to the company's current report on Form 8-K filed September 10, 2008 and incorporated herein by reference).
- 10.35 Offer Letter from Orthofix International N.V. to Robert S. Vaters dated September 5, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed September 10, 2008 and incorporated herein by reference).
- 10.36\*+ Letter Agreement between Orthofix Inc. and Oliver Burckhardt dated August 28, 2008.
- 10.37\* Notice of Termination from Orthofix Inc. to Oliver Burckhardt dated August 27, 2008.
- 10.38 Employment Agreement between Orthofix Inc. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed October 15, 2008 and incorporated herein by reference).

10.39 Second Amended and Restated Performance Accelerated Stock Options Agreement between Orthofix International N.V. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed October 15, 2008 and incorporated herein by reference).

10.40 Nonqualified Stock Option Agreement between Orthofix International N.V. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed October 15, 2008 and incorporated herein by reference).

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

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

32.1\* Section 1350 Certification of Chief Executive Officer.

32.2\* Section 1350 Certification of Chief Financial Officer.

\* Filed herewith.

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



Table of Contents

SIGNATURES

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

ORTHOFIX INTERNATIONAL N.V.

Date: November 10, 2008

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

Date: November 10, 2008

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