

ORTHOFIX INTERNATIONAL N V  
Form 10-Q  
November 07, 2007

---

**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, 2007

OR

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

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

Commission File Number: 0-19961

**ORTHOFIX INTERNATIONAL N.V.**

(Exact name of registrant as specified in its charter)

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

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

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

N/A  
(Zip Code)

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

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

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

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

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 5, 2007, 16,935,239 shares of common stock were issued and outstanding.

---

## Table of Contents

<b>PART I</b>	<b><u>FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1.	<u>Condensed Financial Statements</u>	3
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	31
Item 4.	<u>Controls and Procedures</u>	32
<b>PART II</b>	<b><u>OTHER INFORMATION</u></b>	<b>33</b>
Item 1.	<u>Legal Proceedings</u>	33
Item 1A.	<u>Risk Factors</u>	34
Item 6.	<u>Exhibits</u>	35
<b><u>SIGNATURES</u></b>		<b>38</b>

## Forward-Looking Statements

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

Factors that could cause actual results to differ materially from those indicated by the forward-looking statements or that could contribute to such differences include, but are not limited to, unanticipated expenditures, changing relationships with customers, suppliers and strategic partners, unfavorable results in litigation matters, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, changes to governmental regulation of medical devices, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry and the economy, currency or interest rate fluctuations and the other risks described under Item 1A – “Business – Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and Part II, Item 1A – “Risk Factors” in this Form 10-Q.

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

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

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
	(Unaudited)	(Note 2)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 23,562	\$ 25,881
Restricted cash	11,570	7,300
Trade accounts receivable, net	118,793	104,662
Inventories, net	89,810	70,395
Deferred income taxes	9,020	6,971
Prepaid expenses and other current assets	25,109	18,759
Total current assets	277,864	233,968
Securities and other investments	4,082	4,082
Property, plant and equipment, net	31,532	25,311
Patents and other intangible assets, net	255,609	261,159
Goodwill	319,243	313,070
Deferred taxes and other long-term assets	31,120	24,695
Total assets	\$ 919,450	\$ 862,285
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Bank borrowings	\$ 8,381	\$ 78
Current portion of long-term debt	3,300	3,334
Trade accounts payable	22,341	23,544
Other current liabilities	49,258	34,084
Total current liabilities	83,280	61,040
Long-term debt	305,584	312,055
Deferred income taxes	93,558	95,019
Other long-term liabilities	6,017	1,536
Total liabilities	488,439	469,650
Contingencies (Note 17)		
Shareholders' equity:		
Common shares (16,676,753 and 16,445,859 shares issued at September 30, 2007 and December 31, 2006, respectively)	1,668	1,645
Additional paid-in capital	144,243	128,297
Retained earnings	268,716	248,433
Accumulated other comprehensive income	16,384	14,260
Total shareholders' equity	431,011	392,635
Total liabilities and shareholders' equity	\$ 919,450	\$ 862,285

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

**Table of Contents**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net sales	\$ 121,120	\$ 83,368	\$ 361,488	\$ 249,219
Cost of sales	30,742	21,007	94,546	63,665
Gross profit	90,378	62,361	266,942	185,554
Operating expenses (income)				
Sales and marketing	47,055	36,277	138,949	98,985
General and administrative	16,908	11,747	49,619	36,337
Research and development	5,953	42,865	18,313	48,550
Amortization of intangible assets	4,671	1,929	13,710	5,408
KCI settlement, net of litigation costs	-	-	-	(1,093)
	74,587	92,818	220,591	188,187
Operating income (loss)	15,791	(30,457)	46,351	(2,633)
Interest (expense) income, net	(5,666)	(482)	(17,200)	164
Other income (expense), net	529	(508)	287	(753)
Income (loss) before minority interests and income taxes	10,654	(31,447)	29,438	(3,222)
Minority interests	(10)	-	(53)	-
Income (loss) before income taxes	10,644	(31,447)	29,385	(3,222)
Income tax expense	(2,616)	(3,970)	(7,902)	(11,221)
Net income (loss)	\$ 8,028	\$ (35,417)	\$ 21,483	\$ (14,443)
Net income (loss) per common share - basic	\$ 0.48	\$ (2.19)	\$ 1.30	\$ (0.90)
Net income (loss) per common share - diluted	\$ 0.48	\$ (2.19)	\$ 1.27	\$ (0.90)
Weighted average number of common shares - basic	16,639,019	16,193,086	16,546,385	16,084,388
Weighted average number of common shares - diluted	16,889,303	16,193,086	16,925,084	16,084,388

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

**Table of Contents****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006**

(Unaudited, U.S. Dollars, in thousands)	<b>2007</b>	<b>2006</b>
Cash flows from operating activities:		
Net income (loss)	\$ 21,483	\$ (14,443)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	21,334	10,937
Amortization of debt costs	523	316
In process research & development	-	40,000
Provision for doubtful accounts	3,532	4,330
Deferred taxes	(3,919)	(8,808)
Stock-based compensation	8,006	5,416
Amortization of step up of fair value in inventory acquired from Blackstone	2,718	-
Other	(1,328)	1,261
Change in operating assets and liabilities:		
Restricted cash	(4,270)	(5,762)
Accounts receivable	(14,829)	(7,397)
Inventories	(19,086)	(7,621)
Prepaid expenses and other current assets	(5,976)	(4,994)
Accounts payable	(2,707)	7,551
Current liabilities	8,277	(29,745)
Net cash provided by (used in) operating activities	13,758	(8,959)
Cash flows from investing activities:		
Investments in affiliates and subsidiaries	(2,117)	(336,808)
Capital expenditures	(23,752)	(6,769)
Net cash used in investing activities	(25,869)	(343,577)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	6,799	10,742
Tax benefit on non-qualified stock options	1,164	2,048
Repayment of long-term debt	(6,524)	(15,044)
Payment of debt issuance cost	-	(5,708)
Proceeds from long-term debt	19	330,000
Proceeds from bank borrowings	7,870	3,047
Net cash provided by financing activities	9,328	325,085
Effect of exchange rate changes on cash	464	779
Net decrease in cash and cash equivalents	(2,319)	(26,672)
Cash and cash equivalents at the beginning of the year	25,881	63,786
Cash and cash equivalents at the end of the period	\$ 23,562	\$ 37,114

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

**Table of Contents**

NOTES TO THE CONDENSED UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: BUSINESS

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

NOTE 2: BASIS OF PRESENTATION

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures, normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States, have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. The balance sheet at December 31, 2006 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, 2006.

**Table of Contents**

## NOTE 3:

## RECENTLY ISSUED ACCOUNTING STANDARDS

On January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"), which clarifies the accounting for uncertainty in income taxes. As a result of the implementation of FIN 48, the Company recognized \$1.2 million in additional liability for unrecognized tax benefits (including interest and penalties), which was accounted for as a reduction to the January 1, 2007 balance of retained earnings. As of September 30, 2007, the Company's unrecognized tax benefits totaled \$1.5 million including interest of \$0.2 million. All of the unrecognized tax benefits recorded would affect the Company's effective tax rate if recognized.

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	N/A	2005-2006
Various States	1996-2005	1996-2005
Brazil	2004-2005	2005-2006
Cyprus	N/A	2005-2006
France	N/A	2002-2006
Germany	2003-2005	2006
Italy	N/A	2002-2006
Mexico	N/A	2000-2006
Netherlands	N/A	2004-2006
Puerto Rico	N/A	N/A
Seychelles	N/A	N/A
Switzerland	N/A	2004-2006
United Kingdom	N/A	2003-2006

The Company recognizes potential 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.

**Table of Contents**

## NOTE 4:

## STOCK-BASED COMPENSATION

The Company accounts for its stock-based compensation plans in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 123(R), “Share-Based Payment”, using the modified prospective transition method. Under SFAS No. 123(R), all stock-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 income statement over the requisite service period. Commencing in June 2007, the Company offered restricted shares in addition to stock options as a form of stock-based compensation.

The following table shows the detail of stock-based compensation by line item in the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2007 and 2006:

(In US\$ thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Cost of sales	\$ 113	\$ 83	\$ 293	\$ 151
Sales and marketing	800	472	1,993	882
General and administrative (1)	1,846	822	4,978	3,916
Research and development	126	136	742	467
Total	\$ 2,885	\$ 1,513	\$ 8,006	\$ 5,416

(1) The nine months ended September 30, 2006 amount includes \$656 of stock-based compensation from the accelerated vesting of options associated with the transition of senior management in the first quarter of 2006.

## NOTE 5:

## RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform to the 2007 presentation. The reclassifications have no effect on previously reported net income (loss) or shareholders’ equity.

**Table of Contents**

## NOTE 6:

## INVENTORY

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

Inventories were as follows:

(In US\$ thousands)	September 30, 2007	December 31, 2006
Raw materials	\$ 10,275	\$ 8,384
Work-in-process	8,698	6,665
Finished goods	39,719	34,901
Field inventory (as described above)	9,749	7,485
Consignment inventory	28,054	20,173
	96,495	77,608
Less reserve for obsolescence	(6,685)	(7,213)
	\$ 89,810	\$ 70,395

## NOTE 7:

## BLACKSTONE ACQUISITION

The following acquisition was recorded using the purchase method of accounting:

*Blackstone Acquisition*

On September 22, 2006, the Company purchased 100% of the stock of Blackstone Medical, Inc. ("Blackstone") for a purchase price of \$333.0 million plus acquisition costs. The acquisition and related costs were financed with approximately \$330.0 million of senior secured bank debt, as described in Note 10, and cash on hand. Blackstone, a company based in Springfield, Massachusetts, which was privately held when acquired by the Company, specializes in the design, development and marketing of spinal implant and related biologic products. Blackstone's product lines include spinal fixating devices including hooks, rods, screws, plates, various spacers and cages and related biologics products.

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

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

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

**Table of Contents**

The final allocation of the purchase price reflects the following:

Current assets, other than cash	\$ 40,101
Fixed assets acquired	2,872
Intangible assets not subject to amortization – registered trademarks	77,000
Intangible assets subject to amortization (12-16 year weighted average useful life):	
Distribution networks (12 – 16 year weighted average useful life)	55,000
Patents (13 year weighted average useful life)	70,000
	244,973
Goodwill (indefinite lived intangible asset)	136,603
In-process research and development	40,000
Deferred tax asset	14,985
Total assets acquired	436,561
Current liabilities	(13,037)
Deferred tax liability	(78,442)
Total liabilities assumed	(91,479)
Net assets acquired	\$ 345,082

The results of Blackstone's operations have been included in the Company's consolidated results of operations from the date of acquisition.

The purchase price has been allocated to assets acquired, purchased in-process research and development and liabilities assumed based on their estimated fair market value at the acquisition date. The amount of the purchase price allocated to purchased in-process research and development was written off at the date of acquisition and resulted in a charge of \$40.0 million. This charge was included in the research and development expense line item on the Consolidated Statements of Operations for the year ended December 31, 2006 and was not deductible for income tax purposes in the United States. Purchased in-process research and development was principally comprised of the value of the Dynamic Stabilization and Cervical Disk which together accounted for 93% of the fair value. The fair value of the in-process research and development was estimated using the discounted earnings method. The Company expects material net cash inflows from the Dynamic Stabilization to commence in 2008 and material net cash inflows from the Cervical Disk to commence in 2012. The nature of the costs expected to complete the Dynamic Stabilization and Cervical Disk include research and development expense and research and development maintenance expense to make modifications and enhancements to the products. The Company expects to incur costs of approximately \$0.7 million for the Dynamic Stabilization in 2007 and approximately \$10.0 million for the Cervical Disk during the period 2007 through 2010. As of September 30, 2007, the Company does not believe there have been any material changes in the assumptions made at the time of acquisition relating to in-process research and development. Of the total Blackstone purchase price, \$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 Orthofix is indemnified. As described in Note 17, the Company has certain contingencies arising from the acquisition that management expects will be reimburseable from the escrow account should the Company have to make a payment to a third party. Management believes that the amount that it will be required to pay relating to the contingencies will not exceed the amount of the escrow account, however there can be no assurance that the contingencies will not exceed the amount of the escrow account.

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



**Table of Contents**

(In US\$ thousands)	Fair value at Acquisition	Remaining Useful Life
Distribution networks	\$ 55,000	12 to 16 Years
Patents	70,000	13 Years
Total definite lived intangible assets	\$ 125,000	

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

## NOTE 8:

## GOODWILL

The change in the net carrying value of goodwill for the period ended September 30, 2007 is as follows:

(In US\$ thousands)	Domestic	Blackstone	Breg	International	Total
At December 31, 2006	\$ 31,793	\$ 132,784	\$ 101,322	\$ 47,171	\$ 313,070
Purchase price adjustment (1)	-	3,819	-	-	3,819
Purchase of minority interest	-	-	-	128	128
Foreign currency	-	-	-	2,226	2,226
At September 30, 2007	\$ 31,793	\$ 136,603	\$ 101,322	\$ 49,525	\$ 319,243

(1) Principally relates to legal fees incurred in connection with the acquisition of Blackstone and related contingencies.

## NOTE 9:

## BANK BORROWINGS

(In US\$ thousands)	September 30, 2007	December 31, 2006
Borrowings under line of credit	\$ 8,381	\$ 78

The weighted average interest rate on borrowings under lines of credit as of September 30, 2007 and December 31, 2006 was 4.80% and 3.00%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The amount available to borrow under the line of credit was 6.2 million Euros at September 30, 2007 and December 31, 2006. As of September 30, 2007, the Company had utilized 5.9 million Euro of its Italian line of credit. The Italian line of credit 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.



**Table of Contents**

## NOTE 10:

## LONG-TERM DEBT

(In US\$ thousands)	September 30, 2007	December 31, 2006
Long-term obligations	\$ 308,700	\$ 315,175
Other loans	184	214
	308,884	315,389
Less current portion	(3,300)	(3,334)
	\$ 305,584	\$ 312,055

On September 22, 2006 the Company's wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. ("Orthofix Holdings"), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million, the proceeds of which, together with cash balances were used for payment of the purchase price of Blackstone; and (2) a six-year revolving credit facility of \$45.0 million. As of September 30, 2007, the Company had no amounts outstanding under the revolving credit facility and \$308.7 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of London Inter-Bank Offered Rate ("LIBOR") plus a margin or prime rate plus a margin. Currently, the term loan is a LIBOR loan, and the margin is 1.75%, which margin is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. The effective interest rate as of September 30, 2007 on the senior secured debt is 6.95%, compared to 7.12% as of December 31, 2006.

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

In conjunction with obtaining the senior secured credit facility and the amendment thereto, the Company incurred debt issuance costs of \$6.2 million. As of September 30, 2007, \$5.2 million of capitalized debt issuance costs is included in other long-term assets compared to \$5.8 million at December 31, 2006.

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. All other subsidiaries of the Company 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, 2007 is \$288.3 million compared to \$247.2 million at December 31, 2006.

## NOTE 11:

## COMMON SHARES

For the nine months ended September 30, 2007, the Company issued 230,894 shares of common stock upon the exercise of outstanding stock options and shares issued pursuant to our employee stock purchase plan for net proceeds of \$6.8 million.

**Table of Contents**

## NOTE 12:

## COMPREHENSIVE INCOME (LOSS)

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

(In US\$ thousands)	Foreign Currency Translation Adjustments	Fair Value of Derivatives	Accumulated Other Comprehensive Income
Balance at December 31, 2006	\$ 14,315	\$ (55)	\$ 14,260
Unrealized loss on derivative instrument, net of tax of \$161	-	(575)	(575)
Foreign currency translation adjustment	2,699	-	2,699
Balance at September 30, 2007	\$ 17,014	\$ (630)	\$ 16,384

(In US\$ thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net income (loss)	\$ 8,028	\$ (35,417)	\$ 21,483	\$ (14,443)
Other comprehensive income (loss):				
Unrealized loss on derivative instrument, net of tax	(367)	-	(575)	-
Foreign currency translation adjustment	1,227	397	2,699	6,838
Total comprehensive income (loss)	\$ 8,888	\$ (35,020)	\$ 23,607	\$ (7,605)

## 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. Concurrent with the acquisition of Blackstone, the Company redefined its business segments and market sectors. All prior period information presented has been restated to conform to the new segments and market sectors. The Company is comprised of the following segments:

*Orthofix Domestic*

Orthofix Domestic ("Domestic") consists of operations in the United States of Orthofix Inc., which 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 biologic products. Blackstone's operating loss includes amortization of acquired intangible assets and inventory which has been stepped-up in value for the Blackstone acquisition. Blackstone distributes its products through a network of domestic and international distributors, sales representatives and affiliates.

**Table of Contents*****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 Sports Medicine products through a network of domestic and international distributors, sales representatives and affiliates.

***Orthofix International***

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

***Group Activities***

Group Activities are comprised of Orthofix International N.V., the ultimate parent corporation and Orthofix Holdings, the U.S. holding company.

The following tables present external and intersegment sales by 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	
	2007	2006	2007	2006
Domestic	\$ 41,971	\$ 37,952	\$ 858	\$ 818
Blackstone	29,448	-	1,012	-
Breg	21,206	18,667	1,337	406
International	28,495	26,749	5,958	10,072
Total	\$ 121,120	\$ 83,368	\$ 9,165	\$ 11,296

For the nine month period ended September 30:

(In US\$ thousands)	External Sales		Intersegment Sales	
	2007	2006	2007	2006
Domestic	\$ 122,718	\$ 113,185	\$ 3,137	\$ 2,476
Blackstone	85,859	-	2,449	-
Breg	61,522	55,901	2,561	1,027
International	91,389	80,133	22,108	44,218
Total	\$ 361,488	\$ 249,219	\$ 30,255	\$ 47,721

**Table of Contents**

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

<b>Operating Income (Loss)</b> <b>(In US\$ thousands)</b>	<b>Three Months Ended</b> <b>September 30,</b>		<b>Nine Months Ended</b> <b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Domestic	\$ 14,050	\$ 7,391	\$ 42,124	\$ 26,430
Blackstone	(816)	(40,271)	(2,164)	(40,271)
Breg	2,686	1,392	6,013	4,926
International	4,230	4,594	14,824	16,509
Group Activities	(3,735)	(3,258)	(11,644)	(8,546)
Eliminations	(624)	(305)	(2,802)	(1,681)
Total	\$ 15,791	\$ (30,457)	\$ 46,351	\$ (2,633)

The following tables present sales by market sector for the three and nine month periods ended September 30, 2007 and 2006:

<b>(In US\$ thousands)</b>	<b>Sales by Market Sector</b> <b>for the three month period ended September 30, 2007</b>				
	<b>Orthofix</b>	<b>Blackstone</b>	<b>Breg</b>	<b>Orthofix</b>	<b>Total</b>
	<b>Domestic</b>			<b>International</b>	
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
Total	\$ 41,971	\$ 29,448	\$ 21,206	\$ 28,495	\$ 121,120

**Table of Contents****Sales by Market Sector****for the three month period ended September 30, 2006**

<b>(In US\$ thousands)</b>	<b>Orthofix Domestic</b>	<b>Blackstone</b>	<b>Breg</b>	<b>Orthofix International</b>	<b>Total</b>
Spine	\$ 29,216	\$ -	\$ -	\$ 66	\$ 29,282
Orthopedics	8,736	-	-	14,749	23,485
Sports Medicine	-	-	18,667	739	19,406
Vascular	-	-	-	5,084	5,084
Other	-	-	-	6,111	6,111
<b>Total</b>	<b>\$ 37,952</b>	<b>\$ -</b>	<b>\$ 18,667</b>	<b>\$ 26,749</b>	<b>\$ 83,368</b>

**Sales by Market Sector****for the nine month period ended September 30, 2007**

<b>(In US\$ thousands)</b>	<b>Orthofix Domestic</b>	<b>Blackstone</b>	<b>Breg</b>	<b>Orthofix International</b>	<b>Total</b>
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
<b>Total</b>	<b>\$ 122,718</b>	<b>\$ 85,859</b>	<b>\$ 61,522</b>	<b>\$ 91,389</b>	<b>\$ 361,488</b>

**Table of Contents**

(In US\$ thousands)	Sales by Market Sector for the nine month period ended September 30, 2006				
	Orthofix Domestic	Blackstone	Breg	Orthofix International	Total
Spine	\$ 86,595	\$ -	\$ -	\$ 186	\$ 86,781
Orthopedics	26,590	-	-	44,552	71,142
Sports Medicine	-	-	55,901	2,018	57,919
Vascular	-	-	-	15,417	15,417
Other	-	-	-	17,960	17,960
Total	\$ 113,185	\$ -	\$ 55,901	\$ 80,133	\$ 249,219

## NOTE 14:

## INCOME TAXES

The difference between the reported provision for income taxes and a provision computed by applying the statutory rates applicable to each subsidiary of the Company is primarily attributable to a discrete tax benefit resulting from tax credits associated with research and development expense. 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 non-deductible foreign losses, the generation of unutilizable net operating losses in various jurisdictions, tax planning associated with the acquisition of Breg and the Section 199 deduction related to income attributable to production activities occurring in the United States.

## NOTE 15:

## EARNINGS PER SHARE

For the three and nine month periods ended September 30, 2007 and 2006, there were no adjustments to net income (loss) (the numerators) for purposes of calculating basic and diluted net income (loss) per common share. The following table sets forth a reconciliation of the share numbers (the denominators) in computing earnings per share in accordance with SFAS No. 128, "Earnings Per Share":

	Three Months Ended September 30, 2007		September 30, 2006	
	2007		2006	
Weighted average common shares - basic	16,639,019	16,193,086	16,546,385	16,084,388
Effect of dilutive securities	250,284	-	378,699	-
Weighted average common shares – diluted	16,889,303	16,193,086	16,925,084	16,084,388

**Table of Contents**

The Company did not include 172,218 and 145,218 options in the diluted shares outstanding calculation for the three and nine month periods ended September 30, 2007, because their inclusion would have been antidilutive or because their exercise price exceeded the average market price of the Company's common stock during the period. For both the three and nine month periods ended September 30, 2006, the Company did not include 680,300 options in the diluted shares outstanding calculation because their inclusion would have been antidilutive or because their exercise price exceeded the average market price of the Company's common stock during the period.

NOTE 16:

DERIVATIVE INSTRUMENT

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, 2007 is \$63.0 million. Under the agreement, the Company pays Euro and receives U.S. dollars based on scheduled cash flows in the agreement. The Company recognized the unrealized loss on the change in fair value of this swap arrangement of \$0.4 million and \$0.6 million, net of tax, within other comprehensive income for the three and nine month periods ended September 30, 2007.

NOTE 17:

CONTINGENCIES

*Litigation*

Effective October 29, 2007, the Company's subsidiary, Blackstone, entered into a settlement agreement with respect to a patent infringement lawsuit captioned Medtronic Sofamor Danek USA Inc., Warsaw Orthopedic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Sofamor Danek Deggendorf, GmbH v. Blackstone Medical, Inc., Civil Action No. 06-30165-MAP, filed on September 22, 2006 in the United States District Court for the District of Massachusetts. In that lawsuit, the plaintiffs had alleged that (i) they were the exclusive licensees of United States Patent Nos. 6,926,718 B1, 6,936,050 B2, 6,936,051 B2, 6,398,783 B1 and 7,066,961 B2 (the "Patents"), and (ii) Blackstone's making, selling, offering for sale, and using within the United States of its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products infringed the Patents, and that such infringement was willful. The Complaint requested both damages and an injunction against further alleged infringement of the Patents. The Complaint did not specifically state an amount of damages. Blackstone denied infringement and asserted that the Patents were invalid. On July 20, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between the Company, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the "Merger Agreement"), for any losses to the Company or Blackstone resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. The Company is unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund. The settlement agreement is not expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows.

On or about July 23, 2007, Blackstone received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks documents for the period January 1, 2000 through July 31, 2006 which is prior to Blackstone's acquisition by the Company. The Company believes that the subpoena concerns the compensation of physician consultants and related matters. Blackstone is cooperating with the government's request and is in the process of responding to the subpoena. The Company is unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General or other governmental authorities as a result

of this investigation or what impact, if any, the outcome of this matter might have on its consolidated financial position, results of operations, or cash flows. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to the Company or Blackstone resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. The Company is unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund.

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

**Table of Contents**

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. 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. The Company believes Blackstone and the Company have meritorious defenses to the claims alleged and the Company intends to defend vigorously against this lawsuit. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to the Company or Blackstone resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. The Company is unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund.

Between January 2007 and May 2007, Orthofix, Inc. and/or Blackstone 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. All three civil lawsuits have recently been served and are pending in the Circuit Court of White County, Arkansas. The Company believes Blackstone and Orthofix, Inc. have meritorious defenses to the claims alleged and we intend to defend vigorously against these lawsuits. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to the Company or Blackstone resulting from one of these three civil lawsuits. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. The Company is unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund.

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

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

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

*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, 2006.

**Table of Contents**

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

The following discussion and analysis addresses our liquidity, financial condition, and the results of our operations for the three and nine months ended September 30, 2007 compared to our results of operations for the three and nine months ended September 30, 2006. 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, 2006.

**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 biologics; 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, other pain management products, 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 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 seasonal trends. 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 2007, we have used derivative instruments to hedge certain foreign currency fluctuation exposures. See Item 3 – "Quantitative and Qualitative Disclosures About Market Risk."

On September 22, 2006, we completed the acquisition of Blackstone Medical, Inc. ("Blackstone"), a privately held company specializing in the design, development and marketing of spinal implant and related biologics products. The purchase price for the acquisition was \$333.0 million, subject to certain closing adjustments, plus transaction costs and other accruals totaling approximately \$12.1 million as of September 30, 2007. The acquisition and related costs were

financed with \$330.0 million of senior secured term debt and cash on hand. Debt issuance costs were approximately \$6.2 million.

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

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

The following tables display net sales by business segment and net sales by market sector. We provide net sales by market sector for information purposes only. We keep our books and records and account for net sales, costs of sales and expenses by business segment. In 2006, concurrent with the acquisition of Blackstone, we redefined our business segments and market sectors. All prior period information has been restated to conform to the new business segments and market sectors.

**Business Segment:**

(In US\$ thousands)	Three Months Ended September 30,			
	2007		2006	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	\$ 41,971	35%	\$ 37,952	46%
Blackstone	29,448	24%	-	-%
Breg	21,206	17%	18,667	22%
International	28,495	24%	26,749	32%
Total	\$ 121,120	100%	\$ 83,368	100%

(In US\$ thousands)	Nine Months Ended September 30,			
	2007		2006	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	\$ 122,718	34%	\$ 113,185	46%
Blackstone	85,859	24%	-	-%
Breg	61,522	17%	55,901	22%
International	91,389	25%	80,133	32%
Total	\$ 361,488	100%	\$ 249,219	100%

**Table of Contents****Market Sector:**

(In US\$ thousands)	Three Months Ended September 30,			
	2007		2006	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Spine	\$ 61,309	51%	\$ 29,282	35%
Orthopedics	26,304	22%	23,485	29%
Sports Medicine	22,075	18%	19,406	23%
Vascular	4,718	4%	5,084	6%
Other	6,714	5%	6,111	7%
Total	\$ 121,120	100%	\$ 83,368	100%

(In US\$ thousands)	Nine Months Ended September 30,			
	2007		2006	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Spine	\$ 178,930	49%	\$ 86,781	35%
Orthopedics	81,933	23%	71,142	29%
Sports Medicine	64,555	18%	57,919	23%
Vascular	15,217	4%	15,417	6%
Other	20,853	6%	17,960	7%
Total	\$ 361,488	100%	\$ 249,219	100%

**Table of Contents**

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
	<b>(%)</b>	<b>(%)</b>	<b>(%)</b>	<b>(%)</b>
Net sales	100	100	100	100
Cost of sales	25	25	26	26
Gross profit	75	75	74	74
Operating expenses (income)				
Sales and marketing	39	44	38	40
General and administrative	14	15	14	15
Research and development	5	51*	5	20*
Amortization of intangible assets	4	2	4	2
KCI settlement, net of litigation costs	-	-	-	(1)
Total operating income (loss)	13	(37)	13	(1)
Net income (loss)	7	(43)	6	(6)

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

**Three Months Ended September 30, 2007 Compared to Three Months Ended September 30, 2006**

Net sales increased 45% to \$121.1 million for the third quarter of 2007 compared to \$83.4 million for the third quarter of 2006. The impact of foreign currency increased sales by \$1.5 million during the third quarter of 2007 as compared to the third quarter of 2006.

*Sales by Business Segment:*

Net sales in Domestic increased to \$42.0 million in the third quarter of 2007 compared to \$38.0 million in the third quarter of 2006, an increase of 11%. Domestic represented 35% of total net sales during the third quarter of 2007 and 46% of total net sales for the third quarter of 2006. The increase in Domestic sales was partially the result of a 8% increase in sales in the Spine market sector. This increase continues to be driven by our Spinal-Stim® and Cervical-Stim® products. The Cervical-Stim® continues to be the only FDA-approved stimulation device for the enhancement of fusion in the cervical spine. The Orthopedic market sector sales increased 18% due to increased sales of internal fixation products and a 26% increase in sales of the Physio-Stim® compared to the third quarter of 2006. These increases were partially offset by a 15% decrease in sales of external fixation products when compared to the third quarter of 2006.

**Domestic Sales by Market Sector:**

	<b>Net Sales for the Three Months Ended September 30,</b>			
<b>(In US\$ thousands)</b>	<b>2007</b>	<b>2006</b>	<b>Growth</b>	
Spine	\$ 31,693	\$ 29,216	8%	

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

Orthopedics	10,278	8,736	18%
Total	\$ 41,971	\$ 37,952	11%

**Table of Contents**

Net sales in Blackstone were \$29.4 million in the third quarter of 2007, which represented 24% of total net sales for the third quarter of 2007. There are no sales for Blackstone for the comparable period of the prior year. All of Blackstone's sales are recorded in our Spine market sector. On a pro forma basis Blackstone sales increased 41% when compared to the third quarter of 2006 and would have represented 20% of pro forma total net sales in third quarter 2006.

Net sales in Breg increased \$2.5 million to \$21.2 million for the third quarter of 2007 compared to \$18.7 million for the third quarter of 2006, an increase of 14%. The increase in sales was primarily due to sales of Breg bracing products which increased 18% from the third quarter of 2006. Our Fusion XT™ products contributed to this increase. Sales of cold therapy products increased 15% compared to third quarter of 2006. These increases were partially offset by a 5% decrease in sales for pain therapy products. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International increased 7% to \$28.5 million in the third quarter of 2007 compared to \$26.7 million in the third quarter of 2006. International net sales represented 24% and 32% of our total net sales in the third quarter of 2007 and the third quarter of 2006, respectively. The impact of foreign currency increased International sales by 6% or \$1.5 million, during the third quarter of 2007 as compared to the third quarter of 2006. International sales in the third quarter of 2007 were also positively impacted by a 9% increase in Orthopedic products due to increased sales of our internal fixation products, including the eight-Plate Guided Growth System®, as well as increased sales of Physio-Stim® and other products used in orthopedic applications. Sales of Breg products within International, included in the Sports Medicine market sector, increased \$0.1 million or 18% when compared to third quarter 2006. International sales in the Vascular market sector, which consist of the A-V Impulse product, decreased \$0.4 million or 7%. Sales of our Other products increased \$0.6 million or 10% when compared to third quarter 2006. These increases were slightly offset by sales of external fixation products which decreased 14% compared to the prior period.

**International Sales by Market Sector:**

(In US\$ thousands)	Net Sales for the Three Months Ended September 30,		
	2007	2006	Growth
Spine	\$ 168	\$ 66	155%
Orthopedics	16,026	14,749	9%
Sports Medicine	869	739	18%
Vascular	4,718	5,084	(7)%
Other	6,714	6,111	10%
Total	\$ 28,495	\$ 26,749	7%

***Sales by Market Sector:***

Sales of Spine products increased 109% to \$61.3 million in the third quarter of 2007 compared to \$29.3 million in the third quarter of 2006. The increase is primarily due to the addition of Blackstone product sales and sales growth of spinal stimulation products in the United States. The Cervical-Stim® continues to be the only FDA-approved device for the enhancement of fusion in the cervical spine.

Sales of our Orthopedic products increased 12% to \$26.3 million in the third quarter of 2007 compared to \$23.5 million in the third quarter of 2006. The increase of \$2.8 million was attributable to sales of internal fixation devices including the eight-Plate Guided Growth System® which increased 74%, Physio-Stim® which increased 28% and sales of other products used in orthopedic applications which increased 142%. These increases were partially offset by sales of external fixation products which decreased 14% compared to the prior period.

**Table of Contents**

Sales of our Sports Medicine products increased 14% to \$22.1 million in the third quarter of 2007 compared to \$19.4 million in the third quarter of 2006. As discussed above, the increase in sales is primarily due to sales of our Breg bracing products and cold therapy, particularly the Fusion™ XT knee brace as well as increased sales of Breg products in International.

Sales of our Vascular products decreased 7% to \$4.7 million in the third quarter of 2007 compared to \$5.1 million in the third quarter of 2006. The \$0.4 million decrease in A-V Impulse sales was due to weaker sales in the US market.

Sales of Other products grew 10% to \$6.7 million in the third quarter of 2007 compared to \$6.1 million in the third quarter of 2006. The increase was primarily due to an increase in sales of distributed products and airway management products.

*Gross Profit* - Our gross profit increased 45% to \$90.4 million in the third quarter of 2007, from \$62.4 million in the third quarter of 2006. The increase was primarily due to the increase of 45% in net sales. Gross profit as a percent of net sales in the third quarter 2007 was 74.6% compared to 74.8% in the third quarter of 2006. During the third quarter, we experienced negative impacts from the amortization of the step-up in inventory associated with the Blackstone acquisition and from negative foreign currency impacts which were slightly offset by a reversal of a previously recorded accrual made in connection with one of our distributors. Excluding the favorable benefit to gross margins in the third quarter of 2007, gross margins would have been 73.9%. The step-up in the Blackstone inventory from purchase accounting is now fully amortized.

*Sales and Marketing Expenses* - Sales and marketing expenses, which includes commissions, royalties and bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$10.8 million to \$47.1 million in the third quarter of 2007 compared to \$36.3 million in the third quarter of 2006. As a percent of sales, sales and marketing expenses were 38.8% in the third quarter of 2007 compared to 43.5% for the prior year. Sales and marketing expense in the third quarter of 2006 included the impact of approximately \$4.7 million of monthly fees associated with the termination of the Medtronic Sofamor Danek (“Danek”) marketing agreement. Excluding these fees, the sales and marketing as a percent of sales in the third quarter of 2006 was 37.9%. The year-over-year increase in sales and marketing as a percent of sales, excluding the impact of the termination of the Danek agreement is primarily attributable to the inclusion of Blackstone sales and marketing expense.

*General and Administrative Expense*— General and administrative expense increased \$5.2 million in the third quarter of 2007 to \$16.9 million compared to \$11.7 million in the third quarter of 2006. The increase was primarily attributable to the inclusion of Blackstone general and administrative expense of \$4.1 million for which there was no comparable cost in the third quarter of 2006. General and administrative expense as a percent of sales slightly decreased to 14.0% for the third quarter 2007 compared to 14.1% in the prior year.

*Research and Development Expense* - Research and development expense decreased \$36.9 million in the third quarter of 2007 to \$6.0 million compared to \$42.9 million in the third quarter of 2006. Research and development expense in the third quarter of 2006 included a charge of \$40.0 million related to the write-off of in-process research and development resulting from the Blackstone acquisition. Approximately \$3.2 million is related to Blackstone, for which there was no comparable cost in the prior year.

*Amortization of Intangible Assets*— Amortization of intangible assets increased \$2.8 million in the third quarter of 2007 to \$4.7 million compared to \$1.9 million in the third quarter of 2006. Amortization expense included \$2.8 million related to amortization of intangible assets acquired in the Blackstone acquisition.

*Interest Income (Expense), net* – Interest expense, net was \$5.7 million in the third quarter of 2007 compared to \$0.5 million in the third quarter of 2006. Interest expense for the third quarter of 2007 included interest expense of \$5.6

million related to the senior secured term loan used to finance the Blackstone acquisition.

*Other Income (Expense), net* – Other income, net was \$0.5 million for the third quarter of 2007 compared to other expense of \$0.5 million in the third quarter 2006. The other income in the third quarter of 2007 was due to foreign exchange gains resulting from the weakening during the quarter of the U.S. Dollar as contrasted to the opposite effect in the third quarter 2006.

**Table of Contents**

**Income Tax Expense**— Our estimated worldwide effective tax rate was 24.6% and 12.6% during the third quarter of 2007 and 2006, respectively. The effective tax rates for the third quarter of 2007 included a tax credit for research and development expense relating to 2003. Without this discrete item our estimated worldwide effective tax rate for the third quarter of 2007 was 26.7% due to the positive effects of our European restructuring, research and development tax credits, tax planning associated with the acquisition of Breg, and an increase in the domestic production deduction, which were partially offset by non-deductible foreign losses and the generation of unutilizable net operating losses in various jurisdictions which negatively affected our tax rate. The effective tax rate for the third quarter 2006 reflects the non-deductibility, for tax purposes, of the \$40.0 million purchased in-process research and development charge associated with the Blackstone acquisition. Excluding the charge for in-process research and development, our effective tax rate was 46% due to negative effects of our European restructuring, tax adjustments in foreign jurisdictions and a higher percentage of income being earned in the United States, a higher tax jurisdiction.

**Net Income (Loss)**— Net income for the third quarter of 2007 was \$8.0 million, or \$0.48 per basic share and \$0.48 per diluted share, compared to net loss of \$35.4 million, or \$2.19 per basic share and \$2.19 per diluted share, for the third quarter of 2006. The weighted average number of basic common shares outstanding was 16,639,019 and 16,193,086 during the third quarter of 2007 and 2006, respectively. The weighted average number of diluted common shares outstanding was 16,889,303 and 16,193,086 during the third quarter of 2007 and 2006, respectively.

**Nine Months Ended September 30, 2007 Compared to Nine Months Ended September 30, 2006**

Net sales increased 45% to \$361.5 million for the first nine months of 2007 compared to \$249.2 million for the first nine months of 2006. The impact of foreign currency increased sales by \$5.5 million during the first nine months of 2007 as compared to the first nine months of 2006.

***Sales by Business Segment:***

Net sales in Domestic increased to \$122.7 million in the first nine months of 2007 compared to \$113.2 million in the first nine months of 2006, an increase of 8%. Domestic represented 34% of total net sales during the first nine months of 2007 and 46% of total net sales for the first nine months of 2006. The increase in Domestic sales was partially the result of a 7% increase in sales in the Spine market sector. This increase continues to be driven by the only FDA-approved stimulator for the cervical spine, the Cervical-Stim®. The Orthopedic market sector sales increased 13% due to sales of internal fixation products and a 17% increase in sales of the Physio-Stim® compared to the first nine months of 2006. These increases were partially offset by a 9% decrease in sales of external fixation products when compared to the first nine months of 2006.

**Domestic Sales by Market Sector:**

(In US\$ thousands)	Net Sales for the Nine Months Ended September 30,			Growth
	2007	2006		
Spine	\$ 92,650	\$ 86,595		7%
Orthopedics	30,068	26,590		13%
Total	\$ 122,718	\$ 113,185		8%

Net sales in Blackstone were \$85.9 million in the first nine months of 2007, which represented 24% of total net sales for the first nine months of 2007. There are no sales for Blackstone for the comparable period of the prior year. All of Blackstone's sales are recorded in our Spine market sector. On a pro forma basis Blackstone sales increased 40% when compared to the first nine months of 2006 and would have represented 20% of pro forma total net sales in first nine months 2006.

**Table of Contents**

Net sales in Breg increased \$5.6 million to \$61.5 million for the first nine months of 2007 compared to \$55.9 million for the first nine months of 2006, an increase of 10%. The increase in sales was primarily due to sales of Breg bracing products which increased 12% from the first nine months of 2006. Our Fusion XT™ products contributed to this increase. Sales of cold therapy products increased 13% compared to the first nine months of 2006. These increases were partially offset by a 11% decrease in sales for pain therapy products. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International increased 14% to \$91.4 million in the first nine months of 2007 compared to \$80.1 million in the first nine months of 2006. International net sales represented 25% and 32% of our total net sales in the first nine months of 2007 and the first nine months of 2006, respectively. The impact of foreign currency increased International sales by 6%, or \$5.3 million, during the first nine months of 2007 as compared to the first nine months of 2006. Sales in the first nine months of 2007 were also positively affected by a \$1.9 million sale to a distributor in Latin America. International sales in the first nine months of 2007 were also positively impacted by a 16% increase in sales of Orthopedic products due to increased sales of our internal fixation products, including the eight-Plate Guided Growth System®, as well as increased sales of Physio-Stim® and other products used in orthopedic applications. Sales of Breg products internationally which are included in the Sports Medicine market sector, increased \$1.0 million or 50% when compared to the first nine months of 2006. International sales in the Vascular market sector, which consist of the A-V Impulse product, decreased \$0.2 million. Sales of our Other products increased \$2.9 million when compared to the first nine months of 2006.

**International Sales by Market Sector:**

(In US\$ thousands)	Net Sales for the Nine Months Ended September 30,			Growth
	2007	2006		
Spine	\$ 421	\$ 186		126%
Orthopedics	51,865	44,552		16%
Sports Medicine	3,033	2,018		50%
Vascular	15,217	15,417		(1)%
Other	20,853	17,960		16%
Total	\$ 91,389	\$ 80,133		14%

*Sales by Market Sector:*

Sales of Spine products increased 106% to \$179.0 million in the first nine months of 2007 compared to \$86.8 million in the first nine months of 2006. The increase is primarily due to the addition of Blackstone product sales and sales growth of spine stimulation products in the United States. Spine stimulation sales increased 7% compared to the first nine months of 2006. The Cervical-Stim® continues to be the only FDA-approved stimulation device for the enhancement of fusion in the cervical spine.

Sales of our Orthopedic products increased 15% to \$81.9 million in the first nine months of 2007 compared to \$71.1 million in the first nine months of 2006. The increase of \$10.8 million was attributable to sales of internal fixation devices including the eight-Plate Guided Growth System® which increased 95% and sales of other products used in orthopedic applications which increased 108%. These increases were partially offset by sales of external fixation products which decreased 6% compared to the prior period.



**Table of Contents**

Sales of our Sports Medicine products increased 11% to \$64.6 million in the first nine months of 2007 compared to \$57.9 million in the first nine months of 2006. As discussed above, the increase in sales is primarily due to sales of our Breg bracing products and cold therapy, particularly the Fusion™ XT knee brace as well as increased sales of Breg products in International.

Sales of our Vascular products decreased 1% to \$15.2 million in the first nine months of 2007 compared to \$15.4 million in the first nine months of 2006. This decrease was due to a \$0.2 million decrease in A-V Impulse sales due to weaker sales in the US market.

Sales of Other products grew 16% to \$20.9 million in the first nine months of 2007 compared to \$18.0 million in the first nine months of 2006. The increase was primarily due to an increase in sales of distributed products and airway management products.

*Gross Profit* - Our gross profit increased 44% to \$266.9 million in the first nine months of 2007, from \$185.6 million in the first nine months of 2006. The increase was primarily due to the increase of 45% in net sales. Gross profit as a percent of net sales in the first nine months of 2007 was 73.8% compared to 74.5% in the first nine months of 2006. During the first nine months of 2007, we experienced negative impacts from the amortization of the step-up in inventory associated with the Blackstone acquisition and from negative foreign currency impacts which were slightly offset by a reversal of a previously recorded accrual made in connection with one of our distributors. Excluding the favorable benefit to, gross margins in the first nine months of 2007, gross margins would have been 73.6%. The step-up in the Blackstone inventory from purchase accounting is now fully amortized.

*Sales and Marketing Expenses* - Sales and marketing expenses, which include commissions, royalties and bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$39.9 million to \$138.9 million in the first nine months of 2007 compared to \$99.0 million in the first nine months of 2006. As a percent of sales, sales and marketing expenses were 38.4% in the first nine months of 2007 compared to 39.7% for the prior year. Sales and marketing expense in the first nine months of 2006 included the impact of approximately \$4.7 million of monthly fees associated with the termination of a marketing services agreement formerly in place between the Company's subsidiary Orthofix Inc. and Medtronic Sofamor Danek. Excluding these fees, sales and marketing as a percent of sales for the first nine months of 2006 was 37.8%. The year-over-year increase in sales and marketing as a percent of sales, excluding the impact of the termination of the Danek agreement is primarily attributable to the inclusion of Blackstone sales and marketing expense.

*General and Administrative Expense*— General and administrative expense increased \$13.3 million in the first nine months of 2007 to \$49.6 million compared to \$36.3 million in the first nine months of 2006. The increase is primarily attributable to the inclusion of Blackstone general and administrative expense of \$11.5 million for which there was no comparable cost in the first nine months of 2006. General and administrative expense as a percent of sales decreased to 13.7% for the third quarter 2007 compared to 14.6% in the prior year reflecting leverage obtained from spreading general and administrative costs over a larger revenue base after the Blackstone acquisition.

*Research and Development Expense* - Research and development expense decreased \$30.3 million in the first nine months of 2007 to \$18.3 million compared to \$48.6 million in the first nine months of 2006. Research and development expense in the first nine months of 2006 included a charge of \$40.0 million related to the write-off of in-process research and development resulting from the Blackstone acquisition. Approximately \$9.4 million is related to Blackstone, for which there was no comparable cost in the prior year.

*Amortization of Intangible Assets*— Amortization of intangible assets increased \$8.3 million in the first nine months of 2007 to \$13.7 million compared to \$5.4 million in the first nine months of 2006. Amortization expense included \$8.3 million related to amortization of intangible assets acquired in the Blackstone acquisition.

*KCI Settlement, Net of Litigation Costs*– The gain, net of litigation costs, on the settlement of the KCI litigation in the first nine months of 2006 was \$1.1 million for which there was no comparable gain in the first nine months of 2007.

*Interest Income (Expense), net* – Interest expense, net was \$17.2 million in the first nine months of 2007 compared to \$0.2 million of interest income in the first nine months of 2006. Interest expense for the first nine months of 2007 included interest expense of \$16.8 million related to the senior secured term loan used to finance the Blackstone acquisition.

## **Table of Contents**

*Other Income (Expense), net* – Other income, net was \$0.3 million for the first nine months of 2007 compared to other expense of \$0.8 million in the first nine months of 2006. The other income in the first nine months of 2007 was due to foreign exchange gains resulting from the weakening during the first nine months of the U.S. Dollar as contrasted to the opposite effect in the first nine months of 2006.

*Income Tax Expense*– Our estimated worldwide effective tax rate was 26.9% and (348.3)% during the first nine months of 2007 and 2006, respectively. The effective tax rate for the nine months of 2007 included a tax credit for research and development expense relating to 2003. Without this discrete item our estimated worldwide effective tax rate for the nine months of 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 unutilizable net operating losses in various jurisdictions. The effective tax rate for the first nine months of 2006 reflects the non-deductibility, for tax purposes, of the \$40.0 million purchased in-process research and development charged associated with the Blackstone acquisition. Excluding the charge for in-process research and development, our effective tax rate was 31%. Our effective tax rate in the first nine months of 2006 benefited from a one-time tax benefit of \$2.9 million resulting from our election to adopt a new tax provision in Italy. Without this discrete item, our estimated worldwide effective tax rate for the first nine months of 2006 was 38% as result of higher production of pre-tax income being earned in the United States, a higher tax jurisdiction.

*Net Income (Loss)* – Net income for the first nine months of 2007 was \$21.5 million, or \$1.30 per basic share and \$1.27 per diluted share, compared to net loss of \$14.4 million, or \$0.90 per basic share and \$0.90 per diluted share, for the first nine months of 2006. The weighted average number of basic common shares outstanding was 16,546,385 and 16,084,388 during the first nine months of 2007 and 2006, respectively. The weighted average number of diluted common shares outstanding was 16,925,084 and 16,084,388 during the first nine months of 2007 and 2006, respectively.

## **Liquidity and Capital Resources**

Cash and cash equivalents at September 30, 2007 were \$23.6 million. This compares to \$25.9 million at December 31, 2006. In addition, we had \$11.6 million of restricted cash at September 30, 2007 available for use in our U.S. operations as compared to \$7.3 million at December 31, 2006.

Net cash provided by operating activities was \$13.8 million for the first nine months of 2007 compared to net cash used in operating activities of \$9.0 million in the first nine months of 2006. Net cash provided by (used in) operating activities is comprised of net income (loss), non-cash items (including stock-based compensation) and changes in working capital. Net income increased \$35.9 million to \$21.5 million in the first nine months of 2007 from a net loss of \$14.4 million in the comparable 2006 period. Non-cash items decreased \$22.6 million in the first nine months of 2007 compared to the same period in 2006 primarily as a result of the non-cash effect of increased depreciation and amortization related to the Blackstone acquisition and lower deferred tax assets which were offset by decreased in-process research and development costs due the write off of in-process research and development costs associated with the Blackstone acquisition. Working capital accounts consumed \$38.6 million of cash in the first nine months of 2007 compared to \$48.0 million in the same period in 2006. The principal uses of cash for working capital were attributable to increases in accounts receivable and inventory to support additional sales and certain operational initiatives which were partially offset by an increase in other current liabilities. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 90 days at September 30, 2007 compared to 95 days at September 30, 2006 and inventory turns of 1.4 times at September 30, 2007 compared to 2.0 times at September 30, 2006. The lower inventory turns and resultant higher inventory reflect inventory investment to support Blackstone sales, to open an international distribution center and support for new internal fixation products.

Net cash used in investing activities was \$25.9 million during the first nine months of 2007 compared to \$343.6 million during the first nine months of 2006. During the first nine months of 2007, we invested \$23.8 million in capital expenditures of which \$6.2 million were related to the investment in instrumentation and the acquisition of InSWing™ interspinous process spacer patents at Blackstone. In the first nine months of 2007, we also invested \$2.1 million in investment 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 Brazil. On September 22, 2006, we purchased Blackstone for \$333.0 million plus various transaction costs. In addition, during the first nine months of 2006, we invested \$6.8 million in capital expenditures and we paid \$1.1 million to purchase 52% of International Medical Supplies Distribution GmbH, a distributor of Breg products in Germany.

**Table of Contents**

Net cash provided by financing activities was \$9.3 million in the first nine months of 2007 compared to \$325.1 million in the first nine months of 2006. In the first nine months of 2007, we repaid approximately \$6.5 million of principal of the senior secured term loan and borrowed \$7.9 million to support working capital in our Italian subsidiary. In addition, we received net proceeds of \$6.8 million from the issuance of 230,894 shares of our common stock upon the exercise of stock options and shares issued pursuant to our employee stock purchase plan. Commencing in June 2007, we offered restricted shares in addition to stock options as a form of stock-based compensation. In the first nine months of 2006, we prepaid the remaining \$14.8 million of the principal of the senior secured term loan, which was obtained to help finance the Breg acquisition. On September 22, 2006, we borrowed \$330.0 million in the form of a new senior secured credit agreement, which along with cash balances were used to finance the acquisition of Blackstone and pay debt issuance and other costs. In addition, we received net proceeds of \$10.7 million from the issuance of 376,376 shares of our common stock upon the exercise of stock options and shares issued pursuant to our employee stock purchase plan and \$2.0 million of related tax benefit in the first nine months of 2006.

On September 22, 2006 our wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. (“Orthofix Holdings”), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million, the proceeds of which, together with cash balances were used for payment of the purchase price of Blackstone; and (2) a six-year revolving credit facility of \$45.0 million. As of September 30, 2007 we had no amounts outstanding under the revolving credit facility and \$308.7 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of London Inter-Bank Offered Rate (“LIBOR”), or prime rate plus a margin, currently LIBOR plus 1.75%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. Our effective interest rate as of September 30, 2007 on our senior secured debt is 6.95%. The Company, certain foreign subsidiaries of the Company, including Colgate Medical Limited (Orthofix Holdings’s immediate parent) and certain of Orthofix Holdings’s direct and indirect subsidiaries, including Orthofix Inc., Breg and Blackstone, have guaranteed the obligations of Orthofix Holdings under the senior secured credit facility. The obligations of Orthofix Holdings under the senior secured credit facility and the guarantors under their guarantees are secured by the pledge of their respective assets located in the United States.

At September 30, 2007, we had outstanding borrowings of \$8.4 million and unused available lines of credit of approximately 0.3 million Euro (\$0.2 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

We will continue to search for viable acquisition candidates that would expand our global presence as well as add additional products appropriate for current distribution channels. An acquisition of another company or product line by us could result in our incurrence of additional debt and contingent liabilities.

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

**Table of Contents**

**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, 2007, we had a currency swap in place to minimize foreign currency exchange risk related to a 46.2 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.

As of September 30, 2007, Orthofix Holdings had \$308.7 million of variable rate term debt represented by borrowings under its senior secured term loan at a floating interest rate of LIBOR or prime rate plus a margin, currently LIBOR plus 1.75%, which is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. The effective interest rate as of September 30, 2007 on the senior secured debt is 6.95%. Based on the balance outstanding under the credit facility as of December 31, 2006 an immediate change of one percentage point in the applicable interest rate on the variable rate debt would cause an increase or decrease in interest expense of approximately \$3.1 million on an annual basis.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Great Britain Pound, Mexican Peso and Brazilian Real. We face cost of goods currency exposure when we produce products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. We face transactional currency exposures when foreign subsidiaries (or the Company itself) enter into transactions, generally on an intercompany basis, denominated in currencies other than their functional currency. As of September 30, 2007, we had an uncovered intercompany receivable denominated in Euro for approximately 6.4 million. We are currently evaluating our options to limit the foreign currency exposure on this receivable.

**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*

In July 2007, we implemented an Enterprise Resource Planning (“ERP”) system at Blackstone, a wholly-owned subsidiary which we acquired on September 22, 2006. The ERP system, developed by Epicor, is expected to improve and enhance internal controls over financial reporting. This ERP system materially changes how transactions are processed at Blackstone.

As a result of the recent acquisition of Blackstone, we are continuing to integrate the processes, systems and controls relating to the acquired subsidiary into our existing system of internal control over financial reporting.

We identified certain business process and control issues at our Brazilian subsidiary which has September 2007 year to date revenues of approximately \$6.5 million and net income of approximately \$0.9 million. We have commenced implementing certain internal controls to address the business process and control issues. We expect these certain internal controls to be in place by December 31, 2007. We have implemented certain additional corporate oversight controls during the third quarter to help minimize the risk of the noted control issues.

Except for the processes, systems, and controls relating to the integration of Blackstone and conversion to the ERP system and certain business process and control issues at our Brazilian subsidiary, there have not been any changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2007 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

Effective October 29, 2007, our subsidiary, Blackstone, entered into a settlement agreement with respect to a patent infringement lawsuit captioned Medtronic Sofamor Danek USA Inc., Warsaw Orthopedic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Sofamor Danek Deggendorf, GmbH v. Blackstone Medical, Inc., Civil Action No. 06-30165-MAP, filed on September 22, 2006 in the United States District Court for the District of Massachusetts. In that lawsuit, the plaintiffs had alleged that (i) they were the exclusive licensees of United States Patent Nos. 6,926,718 B1, 6,936,050 B2, 6,936,051 B2, 6,398,783 B1 and 7,066,961 B2 (the "Patents"), and (ii) Blackstone's making, selling, offering for sale, and using within the United States of its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products infringed the Patents, and that such infringement was willful. The Complaint requested both damages and an injunction against further alleged infringement of the Patents. The Complaint did not specifically state an amount of damages. Blackstone denied infringement and asserted that the Patents were invalid. On July 20, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between us, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the "Merger Agreement"), for any losses to us or Blackstone resulting from this matter. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. We are unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to us from the escrow fund. The settlement agreement is not expected to have a material impact on our consolidated financial position, results of operations or cash flows.

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

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

By order entered on January 4, 2007, the United States District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. 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. We believe Blackstone and the Company have 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 the us or Blackstone resulting from this matter. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. We are unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to us from the escrow fund.

Between January 2007 and May 2007, Orthofix, Inc. and/or Blackstone 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. All three civil lawsuits have recently been served and are pending in the Circuit Court of White County, Arkansas. We believe Blackstone and Orthofix, Inc. have meritorious defenses to the claims alleged and we intend to defend vigorously against these lawsuits. On September 17, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us or Blackstone resulting from one of these three civil lawsuits. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement. We are unable to predict the outcome of the escrow claim or to estimate the amount, if any, that may ultimately be returned to us from the escrow fund.

**Table of Contents**

In addition to the foregoing, 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 us. To date, the representative of the former shareholders of Blackstone and the Company has not objected to approximately \$1.5 million in claims from the escrow fund, with certain claims remaining pending.

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

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

**Item 1A. Risk Factors**

There have been no material changes to our risk factors from the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

**Table of Contents**

**Item 6. Exhibits**

**(a) Exhibits**

Exhibit Number	Description
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
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, 2007 and incorporated herein by reference).
10.1	Orthofix Inc. Employee Stock Purchase Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).
10.2	Orthofix International N.V. Staff Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).
10.3	Form of Performance Accelerated Stock Option under the Staff Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).
10.4	Form of Performance Accelerated Stock Option Inducement Agreement (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2003 and incorporated here in by reference).
10.5	Orthofix International N.V. 2004 Long Term Incentive Plan, as amended and restated (filed as an exhibit to the Company's current report on Form 8-K filed June 26, 2007 and incorporated herein by reference).
10.6	Form of Nonqualified Stock Option Agreement Under the Orthofix International N.V. 2004 Long Term Incentive Plan (filed as an exhibit to the Company's current report on Form S-8 filed August 23, 2007 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 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2007 and incorporated herein by reference).
10.8	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).
10.9	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).
10.10	Employment Agreement, dated as of July 13, 2006, between the Company and Thomas Hein (filed as an exhibit to the Company's annual report on Form 8-K filed July 18, 2006 and incorporated herein by reference).
10.11	Employment Agreement, dated as of November 20, 2003, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2003 and incorporated herein by reference).



**Table of Contents**

- 10.12 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).
- 10.13 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).
- 10.14 Employment Agreement amendment, dated December 29, 2005 between Orthofix International N.V. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed December 30, 2005 and incorporated herein by reference).
- 10.15 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).
- 10.16 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).
- 10.17 Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference).
- 10.18 Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference).
- 10.19 Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference).
- 10.20 Credit Agreement, dated as of September 22, 2006, among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, the several banks and other financial institutions as may from time to time become parties thereunder, and Wachovia Bank, National Association (filed as an exhibit to the Company's current report on Form 8-K filed September 27, 2006 and incorporated herein by reference).
- 10.21 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).

**Table of Contents**

10.23 Description of Orthofix International N.V.'s Annual Incentive Plan including the Form of Participation Letter (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).

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.

**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 7, 2007

By:

/s/ Alan W. Milinazzo

Name: Alan W. Milinazzo

Title: Chief Executive Officer and  
President

Date: November 7, 2007

By:

/s/ Thomas Hein

Name: Thomas Hein

Title: Chief Financial Officer