

ORTHOFIX INTERNATIONAL N V

Form 10-Q

July 29, 2010

Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(Mark one)

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

For the quarterly period ended June 30, 2010

OR

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

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

Commission File Number: 0-19961

**ORTHOFIX INTERNATIONAL N.V.**

(Exact name of registrant as specified in its charter)

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

<b>Netherlands Antilles</b> (State or other jurisdiction of incorporation or organization)	<b>N/A</b> (I.R.S. Employer Identification No.)
<b>7 Abraham de Veerstraat</b>  <b>Curaçao</b>	
<b>Netherlands Antilles</b> (Address of principal executive offices)	<b>N/A</b> (Zip Code)
<b>599-9-4658525</b>	
<b>(Registrant's telephone number, including area code)</b>	

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large Accelerated filer  Accelerated filer

Non-Accelerated filer

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

As of July 26, 2010, 17,641,438 shares of common stock were issued and outstanding.

**Table of Contents****Table of Contents**

## PART I FINANCIAL INFORMATION

Item 1.	<u>Condensed Consolidated Financial Statements</u>	3
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	22
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	35
Item 4.	<u>Controls and Procedures</u>	36

## PART II OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	37
Item 1A.	<u>Risk Factors</u>	41
Item 6.	<u>Exhibits</u>	42
<u>SIGNATURES</u>		47

**Forward-Looking Statements**

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

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

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements  
ORTHOFIX INTERNATIONAL N.V.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(U.S. Dollars, in thousands except share data)	June 30, 2010 (unaudited)	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 19,694	\$ 13,328
Restricted cash	19,309	11,630
Trade accounts receivable, less allowance for doubtful accounts of \$6,608 and \$7,205 at June 30, 2010 and December 31, 2009, respectively	129,449	129,777
Inventories, net	83,585	94,624
Deferred income taxes	21,802	20,286
Prepaid expenses	5,098	4,868
Other current assets	28,245	24,981
Total current assets	307,182	299,494
Investments, at cost	345	345
Property, plant and equipment, net	39,990	38,694
Patents and other intangible assets, net	43,993	47,628
Goodwill	174,444	185,175
Deferred taxes and other long-term assets	24,004	19,137
Total assets	\$ 589,958	\$ 590,473
<b>Liabilities and shareholders equity</b>		
Current liabilities:		
Bank borrowings	\$ 2,796	\$ 2,209
Current portion of long-term debt	3,300	3,332
Trade accounts payable	24,493	23,302
Other current liabilities	51,231	59,210
Total current liabilities	81,820	88,053
Long-term debt	223,450	249,132
Deferred income taxes	6,592	6,115
Other long-term liabilities	2,354	6,904
Total liabilities	314,216	350,204
Contingencies (Note 19)		
Shareholders equity:		
Common shares \$0.10 par value; 50,000,000 shares authorized; 17,620,238 and 17,141,710 issued and outstanding as of June 30, 2010 and December 31, 2009, respectively	1,762	1,714
Additional paid-in capital	190,433	177,246
Retained earnings	81,844	54,119
Accumulated other comprehensive income	1,703	7,190

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

Total shareholders' equity	275,742	240,269
Total liabilities and shareholders' equity	\$ 589,958	\$ 590,473

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

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010 AND 2009**

(Unaudited, U.S. Dollars, in thousands except share and per share data)	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2010	2009	2010	2009
Net sales	\$ 142,845	\$ 137,546	\$ 281,668	\$ 266,520
Cost of sales	34,087	36,909	66,781	69,715
Gross profit	108,758	100,637	214,887	196,805
Operating expenses				
Sales and marketing	57,185	55,272	113,475	107,536
General and administrative	20,372	21,191	41,841	43,875
Research and development	8,370	8,886	15,898	17,973
Amortization of intangible assets	1,410	1,643	2,857	3,276
Loss (gain) on sale of vascular operations	211		(12,339)	
	87,548	86,992	161,732	172,660
Operating income	21,210	13,645	53,155	24,145
Other income (expense), net				
Interest expense, net	(5,445)	(5,831)	(11,290)	(11,948)
Gain on interest rate swap	909	1,036	1,254	1,275
Other income (expense), net	100	425	(231)	102
	(4,436)	(4,370)	(10,267)	(10,571)
Income before income taxes	16,774	9,275	42,888	13,574
Income tax expense	(6,542)	(3,331)	(15,164)	(4,751)
Net income	\$ 10,232	\$ 5,944	\$ 27,724	\$ 8,823
Net income per common share basic	\$ 0.58	\$ 0.35	\$ 1.58	\$ 0.52
Net income per common share diluted	\$ 0.57	\$ 0.35	\$ 1.56	\$ 0.51
Weighted average number of common shares basic	17,579,221	17,107,084	17,534,456	17,105,323
Weighted average number of common shares diluted	17,892,886	17,172,557	17,825,604	17,139,789

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

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****FOR THE SIX MONTHS ENDED JUNE 30, 2010 AND 2009**

(Unaudited, U.S. Dollars, in thousands)	2010	2009
<b>Cash flows from operating activities:</b>		
Net income	\$ 27,724	\$ 8,823
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>		
Depreciation and amortization	10,345	10,614
Amortization of debt costs	117	99
Provision for doubtful accounts	3,843	3,487
Deferred taxes	(2,279)	(1,505)
Share-based compensation	5,448	5,316
Provision for inventory obsolescence	3,933	5,055
Change in fair value of interest rate swap	(1,254)	(1,275)
Gain on sale of vascular operations	(12,339)	
Other	743	966
<b>Change in operating assets and liabilities:</b>		
Restricted cash	(7,757)	(4,592)
Accounts receivable	(9,047)	(10,741)
Inventories	879	(5,655)
Prepaid expenses and other current assets	(4,005)	(2,261)
Accounts payable	2,898	(577)
Current liabilities	(7,458)	9,229
<b>Net cash provided by operating activities</b>	<b>11,791</b>	<b>16,983</b>
<b>Cash flows from investing activities:</b>		
Capital expenditures	(11,881)	(9,153)
Net proceeds from sale of assets, principally vascular operations	24,215	
<b>Net cash provided by (used in) investing activities</b>	<b>12,334</b>	<b>(9,153)</b>
<b>Cash flows from financing activities:</b>		
Repayments of long-term debt	(25,656)	(16,618)
Proceeds from bank borrowings, net	1,023	1,107
Proceeds from issuance of common stock	5,996	7
Cash payment for purchase of minority interest in subsidiary		(1,143)
Tax benefit on non-qualified stock options	1,792	2
<b>Net cash used in financing activities</b>	<b>(16,845)</b>	<b>(16,645)</b>
Effect of exchange rate changes on cash	(914)	139
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>6,366</b>	<b>(8,676)</b>
Cash and cash equivalents at the beginning of the year	13,328	14,594
<b>Cash and cash equivalents at the end of the period</b>	<b>\$ 19,694</b>	<b>\$ 5,918</b>

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





**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****NOTE 1: BUSINESS**

Orthofix International N.V. (the Company) is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical equipment, principally for the Orthopedics products market. The Company is comprised of four reportable segments: Domestic, Spinal Implants and Biologics (formerly referred to as Blackstone), Breg and International. See Note 12 for a description of each segment.

**NOTE 2: BASIS OF PRESENTATION**

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States ( U.S. ) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures, normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S., have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. The balance sheet at December 31, 2009 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. For further information, refer to the Consolidated Financial Statements and Notes thereto of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

**NOTE 3: SHARE-BASED COMPENSATION**

All share-based compensation costs are measured at the grant date, based on the estimated fair value of the award, and are recognized as expense in the statement of operations over the requisite service period. Commencing in June 2007, the Company offered restricted shares in addition to stock options as a form of share-based compensation.

The following table shows the detail of share-based compensation by line item in the Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2010 and 2009:

(US\$ in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2010	2009	June 30, 2010	2009
Cost of sales	\$ 93	\$ 142	\$ 191	\$ 339
Sales and marketing	910	773	1,890	1,665
General and administrative	1,324	1,470	3,147	3,024
Research and development	108	107	220	288
<b>Total</b>	<b>\$ 2,435</b>	<b>\$ 2,492</b>	<b>\$ 5,448</b>	<b>\$ 5,316</b>

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

**NOTE 4: RECLASSIFICATIONS**

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

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 5: INVENTORIES**

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

Inventories were as follows:

(US\$ in thousands)	June 30, 2010	December 31, 2009
Raw materials	\$ 11,675	\$ 11,777
Work-in-process	7,094	6,687
Finished products	50,942	59,812
Field inventory	32,029	31,970
Consignment inventory	8,266	8,259
	110,006	118,505
Less reserve for obsolescence	(26,421)	(23,881)
	\$ 83,585	\$ 94,624

**NOTE 6: GOODWILL**

The changes in the carrying value of goodwill by reportable segment for the period ended June 30, 2010 are as follows:

(US\$ in thousands)	Domestic	Spinal Implants and Biologics	Breg	International	Total
At December 31, 2009	\$ 31,793	\$ 9,367	\$ 99,295	\$ 44,720	\$ 185,175
Disposal <sup>(1)</sup>				(7,031)	(7,031)
Foreign currency				(3,700)	(3,700)
At June 30, 2010	\$ 31,793	\$ 9,367	\$ 99,295	\$ 33,989	\$ 174,444

(1) Sale of the vascular operations - see Note 18 - Sale of Vascular Operations.

**NOTE 7: PATENTS AND OTHER INTANGIBLE ASSETS**

(US\$ in thousands)

December 31,  
2009

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

	<b>June 30, 2010</b>	
<b>Cost</b>		
Patents and developed technologies	\$ 26,551	\$ 27,961
Trademarks definite lived (subject to amortization)	120	119
Trademarks indefinite lived (not subject to amortization)	23,544	23,542
Distribution networks	44,586	44,586
	94,801	96,208
<b>Accumulated amortization</b>		
Patents and developed technologies	(18,010)	(17,499)
Trademarks definite lived (subject to amortization)	(112)	(107)
Distribution networks	(32,686)	(30,974)
<b>Patents and other intangible assets, net</b>	<b>\$ 43,993</b>	<b>\$ 47,628</b>

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Amortization expense for intangible assets is estimated to be approximately \$3.0 million for the remainder of 2010 and \$6.0 million, \$4.7 million, \$1.6 million, \$1.6 million, \$1.1 million and \$2.4 million for the periods ending December 31, 2011, 2012, 2013, 2014, 2015 and 2016 and thereafter, respectively.

**NOTE 8: BANK BORROWINGS**

(US\$ in thousands)	June 30, 2010	December 31, 2009
Borrowings under line of credit	\$ 2,796	\$ 2,209

The weighted average interest rates on borrowings under lines of credit as of June 30, 2010 and December 31, 2009 were 4.11% and 5.15%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 5.0 million Euros (\$6.1 million) and 5.8 million Euros (\$8.2 million) at June 30, 2010 and December 31, 2009, respectively, in its Italian line of credit. This line of credit provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing. This line of credit is unsecured.

**NOTE 9: LONG-TERM DEBT**

(US\$ in thousands)	June 30, 2010	December 31, 2009
Long-term obligations	\$ 226,750	\$ 252,400
Other loans		64
	226,750	252,464
Less current portion	(3,300)	(3,332)
	\$ 223,450	\$ 249,132

On September 22, 2006 the Company's wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. ( Orthofix Holdings ), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone Medical Inc. ( Blackstone ). Certain terms of the senior secured credit facility were amended on September 29, 2008 and February 24, 2010. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million and (2) a six-year revolving credit facility of \$45.0 million. As of June 30, 2010, the Company had \$0.3 million of letters of credit outstanding under the revolving credit facility and \$226.8 million outstanding under the term loan facility. Obligations under the senior secured credit facility can have a floating interest rate of the London Inter-Bank Offered Rate ( LIBOR ) plus a margin, with a LIBOR floor of 3.0%, or prime rate plus a margin. As of June 30, 2010, the entire term loan obligation of \$226.8 million is at the prime rate plus a margin of 3.50%. The effective interest rates on the senior secured credit facility as of June 30, 2010 and December 31, 2009 were 9.0% and 8.8%, respectively.

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

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

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

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's senior secured credit facility. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of June 30, 2010 is \$152.3 million compared to \$143.0 million at

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

December 31, 2009. In addition, the senior secured credit facility restricts the Company and subsidiaries that are not parties to the credit facility from access to cash held by Colgate Medical Limited and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of June 30, 2010 is \$19.3 million compared to \$11.6 million at December 31, 2009.

**NOTE 10: COMMON SHARES**

During the six month period ended June 30, 2010, there were 478,528 shares of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

**NOTE 11: COMPREHENSIVE INCOME (LOSS)**

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

(US\$ in thousands)	Foreign Currency Translation Adjustments	Fair Value of Cross - Currency Swap	Accumulated Other Comprehensive Income/(Loss)
Balance at December 31, 2009	\$ 6,795	\$ 395	\$ 7,190
Unrealized loss on cross-currency swap, net of tax of \$(19)		(194)	(194)
Foreign currency translation adjustment <sup>(1)</sup>	(5,293)		(5,293)
Balance at June 30, 2010	\$ 1,502	\$ 201	\$ 1,703

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

Comprehensive income is comprised of the following components:

(US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net income	\$ 10,232	\$ 5,944	\$ 27,724	\$ 8,823
Other comprehensive income:				
Unrealized gain (loss) on derivative instrument, net of tax	251	(696)	(194)	(2,585)
Foreign currency translation adjustment	(2,396)	6,147	(5,293)	5,221
Total comprehensive income	\$ 8,087	\$ 11,395	\$ 22,237	\$ 11,459



**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 12: BUSINESS SEGMENT INFORMATION**

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

***Domestic***

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

***Spinal Implants and Biologics***

Spinal Implants and Biologics ( Spinal Implants and Biologics ) consists of Blackstone and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Spinal Implants and Biologics specializes in the design, development and marketing of spinal implant and related HCT/P products. Spinal Implants and Biologics distributes its products through a network of domestic and international distributors, sales representatives and affiliates.

***Breg***

Breg, Inc. ( Breg ), based in Vista, California, designs, manufactures and distributes orthopedic products for post-operative reconstruction and rehabilitative patient use and sells its products through a network of domestic and international distributors, sales representatives and affiliates.

***International***

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

***Group Activities***

Group activities are comprised of the operating expenses of Orthofix International N.V. and its U.S. holding company subsidiary, Orthofix Holdings.

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

For the three month period ended June 30:

(US\$ in thousands)	External Sales		Intersegment Sales	
	2010	2009	2010	2009
Domestic	\$ 58,949	\$ 53,635	\$ 1,605	\$ 2,128
Spinal Implants and Biologics	32,385	30,025	717	1,308
Breg	22,197	23,342	1,362	1,383
International	29,314	30,544	5,836	5,788
<b>Total</b>	<b>\$ 142,845</b>	<b>\$ 137,546</b>	<b>\$ 9,520</b>	<b>\$ 10,607</b>





**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

For the six month period ended June 30:

(US\$ in thousands)	External Sales		Intersegment Sales	
	2010	2009	2010	2009
Domestic	\$ 114,335	\$ 103,432	\$ 3,208	\$ 3,708
Spinal Implants and Biologics	61,711	58,544	1,195	1,674
Breg	44,706	46,452	2,648	2,893
International	60,916	58,092	10,771	10,427
<b>Total</b>	<b>\$ 281,668</b>	<b>\$ 266,520</b>	<b>\$ 17,822</b>	<b>\$ 18,702</b>

The following table presents operating income (loss) by segment for the three and six months ended June 30:

Operating Income (Loss) (US\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Domestic	\$ 20,856	\$ 17,853	\$ 38,351	\$ 34,505
Spinal Implants and Biologics	2,433	(6,735) <sup>(1)</sup>	1,967 <sup>(2)</sup>	(14,468) <sup>(3)</sup>
Breg	1,717	2,987	2,736 <sup>(4)</sup>	6,017
International	2,155	3,776	19,311 <sup>(5)</sup>	7,450
Group Activities	(4,903)	(4,685)	(9,006)	(10,157)
Eliminations	(1,048)	449	(204)	798
<b>Total</b>	<b>\$ 21,210</b>	<b>\$ 13,645</b>	<b>\$ 53,155</b>	<b>\$ 24,145</b>

(1) Includes \$2.1 million of research and development expense from collaborative arrangements and \$1.7 million of restructuring charges.

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

(3) Includes \$4.9 million of research and development expense from collaborative arrangements and \$3.0 million of restructuring charges.

(4) Includes \$1.7 million of insurance expense to cover new product liability claims from its former pain management operations sold in 2008.

(5) Includes \$12.3 million gain on the sale of vascular operations (see Note 18).

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following tables present sales by market sector for the three and six months ended June 30, 2010 and 2009:

<b>Sales by Market Sector for the three month period ended June 30, 2010</b>					
(US\$ in thousands)	<b>Spinal Implants and</b>				
	<b>Domestic</b>	<b>Biologics</b>	<b>Breg</b>	<b>International</b>	<b>Total</b>
Spine	\$ 44,951	\$ 32,385	\$	\$ 1,311	\$ 78,647
Orthopedics	13,998			22,643	36,641
Sports Medicine			22,197	933	23,130
Other				4,427	4,427
<b>Total</b>	<b>\$ 58,949</b>	<b>\$ 32,385</b>	<b>\$ 22,197</b>	<b>\$ 29,314</b>	<b>\$ 142,845</b>

<b>Sales by Market Sector for the three month period ended June 30, 2009</b>					
(US\$ in thousands)	<b>Spinal Implants and</b>				
	<b>Domestic</b>	<b>Biologics</b>	<b>Breg</b>	<b>International</b>	<b>Total</b>
Spine	\$ 40,142	\$ 30,025	\$	\$ 565	\$ 70,732
Orthopedics	13,493			19,133	32,626
Sports Medicine			23,342	1,118	24,460
Other				9,728	9,728
<b>Total</b>	<b>\$ 53,635</b>	<b>\$ 30,025</b>	<b>\$ 23,342</b>	<b>\$ 30,544</b>	<b>\$ 137,546</b>

<b>Sales by Market Sector For the six month period ended June 30, 2010</b>					
(US\$ in thousands)	<b>Spinal Implants and</b>				
	<b>Domestic</b>	<b>Biologics</b>	<b>Breg</b>	<b>International</b>	<b>Total</b>
Spine	\$ 86,861	\$ 61,711	\$	\$ 1,756	\$ 150,328
Orthopedics	27,474			45,429	72,903
Sports Medicine			44,706	2,014	46,720
Other				11,717	11,717
<b>Total</b>	<b>\$ 114,335</b>	<b>\$ 61,711</b>	<b>\$ 44,706</b>	<b>\$ 60,916</b>	<b>\$ 281,668</b>

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(US\$ in thousands)	Sales by Market Sector for the six month period ended June 30, 2009				
	Domestic	Spinal		International	Total
		Implants and Biologics	Breg		
Spine	\$ 77,425	\$ 58,544	\$	\$ 891	\$ 136,860
Orthopedics	26,007			36,212	62,219
Sports Medicine			46,452	2,254	48,706
Other				18,735	18,735
<b>Total</b>	<b>\$ 103,432</b>	<b>\$ 58,544</b>	<b>\$ 46,452</b>	<b>\$ 58,092</b>	<b>\$ 266,520</b>

**NOTE 13: RESTRUCTURING CHARGES**

In the fourth quarter of 2008, as part of the Company's strategic plan to strengthen the business, the Company initiated a restructuring plan to improve operations and reduce costs at Blackstone. The plan involved the consolidation of substantially all of Spinal Implants and Biologics operations previously conducted in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and U.S. orthopedics business in the Dallas, TX area. The Company plans to complete the restructuring and consolidation during the third quarter of 2010, at which time the Company anticipates a total restructuring expense of \$3.6 million. During the three and six months ended June 30, 2010, the Company did not record any restructuring charges.

The following table presents changes in the restructuring liability for the activity discussed above, which is included within Other Current Liabilities in the Company's consolidated balance sheets as of June 30, 2010 and December 31, 2009:

(US\$ in thousands)	Severance	Assets Abandoned	Total
Balance at December 31, 2009	\$ 1,826	\$	\$ 1,826
Charges			
Cash Payments	(1,807)		(1,807)
Non-cash Items			
<b>Balance at June 30, 2010</b>	<b>\$ 19</b>	<b>\$</b>	<b>\$ 19</b>

**NOTE 14: INCOME TAXES**

The reported year to date tax provision, as a percentage of income before income taxes, was 35.4%. The principal factors affecting the Company's tax rate are the gain on the sale of the vascular operations and the Company's mix of earnings among various tax jurisdictions. The reported tax rate was also affected by current period losses in certain foreign jurisdictions for which the Company does not currently provide a tax benefit. Without the sale of the vascular operations, the Company's tax rate would have been approximately 38.4%.

As of June 30, 2010, the Company's gross unrecognized tax benefit was \$0.8 million. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within its global operations in income tax expense. As of June 30, 2010, the Company had approximately \$0.4 million accrued for interest and penalties. The entire \$0.8 million of unrecognized tax benefit would affect the Company's effective tax rate if recognized. The Company does not anticipate that the amount of unrecognized tax benefits will change materially over the next twelve months.



**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company is subject to tax examinations in all major taxing jurisdictions in which it operates. The Company files a consolidated income tax return in the U.S. federal jurisdiction and numerous consolidated and separate income tax returns in many state and foreign jurisdictions. The statute of limitations with respect to U.S. federal tax filings is closed for years prior to December 31, 2006. The statute of limitations for the various U.S. state tax filings is closed in most instances for years prior to December 31, 2006. There are certain U.S. state tax statutes open for years from 1999 forward due to current examinations. The statutes of limitations with respect to the major foreign tax filing jurisdictions are generally closed for years prior to December 31, 2005.

**NOTE 15: EARNINGS PER SHARE**

For the three and six months ended June 30, 2010 and 2009, there were no adjustments to net income for purposes of calculating basic and diluted net income per common share. The following table is a reconciliation of the weighted average shares used in the basic and diluted net income per common share computations.

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2010	2009	2010	2009
Weighted average common shares basic	17,579,221	17,107,084	17,534,456	17,105,323
Effect of dilutive securities	313,665	65,473	291,148	34,466
Weighted average common shares diluted	17,892,886	17,172,557	17,825,604	17,139,789

For the three and six months ended June 30, 2010, the Company did not include 1,570,655 and 1,624,755 options, respectively, in the diluted shares outstanding calculation because their inclusion would have been anti-dilutive or because their exercise price exceeded the average market price of the Company's common stock during the period.

For the three and six months ended June 30, 2009, the Company did not include 3,162,373 and 3,189,859 options, respectively, in the diluted shares outstanding calculation because their inclusion would have been anti-dilutive or because their exercise price exceeded the average market price of the Company's common stock during the period.

**NOTE 16: DERIVATIVE INSTRUMENTS**

In 2006, the Company entered into a cross-currency swap agreement to manage its cash flows related to foreign currency exposure for a portion of the Company's intercompany receivable of a U.S. dollar functional currency subsidiary that is denominated in Euro. The derivative instrument, a ten-year fully amortizable agreement with an initial notional amount of \$63.0 million, is scheduled to expire on December 30, 2016. The instrument is designated as a cash flow hedge. The amount outstanding under the agreement as of June 30, 2010 and December 31, 2009 is \$53.5 million. Under the agreement, the Company pays Euro and receives U.S. dollars based on scheduled cash flows in the agreement. The Company recognized an unrealized gain (loss) on the change in fair value of this swap arrangement of \$0.3 million and \$(0.2) million, net of tax, within other comprehensive income in the three and six months ended June 30, 2010, respectively. In 2009, the Company recognized an unrealized loss on the change in fair value of this swap arrangement of \$(0.7) million and \$(2.6) million, net of tax, within other comprehensive income in the three and six months ended June 30, 2009, respectively.

In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. On June 29, 2010, the Company settled the Swap with the financial institution holder of the derivative instrument. As part of the terms of the buyout of the Swap, the Company paid \$4.8 million to the financial institution holder. The Swap provided an economic hedge against fluctuating interest rate exposure on the \$150.0 million portion of outstanding debt it covered had the LIBOR interest rate risen above 3.73%.

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

During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's amended credit facility, the Swap was no longer deemed highly effective. Special hedge accounting was no longer

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

applied and fair value adjustments were reported in current earnings. For the three and six months ended June 30, 2010, the Company recorded a gain of \$0.9 million and \$1.3 million, respectively, in the statement of operations. For the three and six months ended June 30, 2009, the Company recorded an unrealized gain of \$1.0 and \$1.3 million, respectively, in the statement of operations.

As required by ASC Topic 815 Derivatives and Hedging, the tables below disclose the types of derivative instruments the Company owns, the classifications and fair values of these instruments within the balance sheet, and the amount of gain (loss) recognized in other comprehensive income (loss) ( OCI ) or net income.

(US\$ in thousands)

As of June 30, 2010	Fair value: favorable (unfavorable)	Balance sheet location	Amount of gain (loss) recognized in OCI
Cross-currency swap	\$ 5,044	Other long-term assets	\$ (194)
<b>As of June 30, 2009</b>			
Cross-currency swap	\$ (3,200)	Other long-term liabilities	\$ (2,585)
Interest rate swap	\$ (6,700)	Other current liabilities	\$

(US\$ in thousands)	For the three months ended		For the six months ended	
	June 30, 2010	June 30, 2009	June 30, 2010	June 30, 2009
Amount of gain recognized in net income				
Interest rate swap	\$ 909	\$ 1,036	\$ 1,254	\$ 1,275

**NOTE 17: FAIR VALUE MEASUREMENTS**

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

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

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

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

As of June 30, 2010, the Company held certain items that are required to be measured at fair value on a recurring basis. These included cash equivalents, restricted cash, accounts receivable, short-term bank borrowings, accounts payable, long-term secured debt, and a cross-currency derivative contract. Cash equivalents consist of short-term, highly liquid, income-producing investments, all of which have original maturities of 90 days or less, including money-market funds. Restricted cash, accounts receivable, short-term bank borrowings and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company's long-term secured debt carries a floating rate of interest and therefore, the carrying value is considered to approximate the fair value. The derivative instrument is related to the Company's foreign currency hedges.





**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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

(US\$ in thousands)	Balance June 30, 2010	Level 1	Level 2	Level 3
Derivative Financial Instruments <sup>(1)</sup>				
Cash Flow Hedges				
Cross-currency hedge	\$ 5,044	\$	\$ 5,044	\$

<sup>(1)</sup> See Note 16, Derivative Instruments.

**NOTE 18: SALE OF VASCULAR OPERATIONS**

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

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

Pursuant to the APA, the Orthofix Parties agreed to enter into certain transition arrangements at the closing under the APA, including (i) a transition services agreement with the Covidien Parties pursuant to which, among other things, the Orthofix Parties will continue to provide operational support with respect to the transferred assets in certain jurisdictions for a period of up to five months, and (ii) two separate supply agreements with certain of the Covidien Parties pursuant to which, among other things, certain of the Orthofix Parties will provide manufacturing and logistics services on behalf of Covidien with respect to certain ImPads for a period of two years and provide other products for a period of 90 days. During the second quarter of 2010, the Company completed the transition services agreement with the Covidien parties and they agreed to extend one of the supply agreements (which supplies the other products) by an additional 90 days. The Orthofix Parties also agreed to enter into a 5-year noncompetition agreement at closing with respect to the business of the assets being transferred.

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table presents the value of the asset disposition, including the cash purchase price, cash proceeds received, net of litigation costs and gain on the sale of the vascular operations as shown in the Condensed Consolidated Statements of Operations for the six months ended June 30, 2010.

<b>(US\$ in thousands)</b>	<b>Total</b>
Gross cash proceeds received from sale of vascular operations	\$ 27,701
Litigation settlement <sup>(1)</sup>	3,486
<b>Cash proceeds, net of litigation</b>	<b>24,215</b>
Less:	
Transaction related expenses	1,933
Inventory	1,570
Tangible assets	799
Identifiable intangible assets	543
Goodwill	7,031
<b>Pre-tax gain on sale of vascular operations</b>	<b>12,339</b>
<b>Income tax expense</b>	<b>3,498</b>
<b>Net gain on sale of vascular operations</b>	<b>\$ 8,841</b>

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

**NOTE 19: CONTINGENCIES*****Litigation***

On or about July 23, 2007, our subsidiary, Blackstone Medical Inc. ( Blackstone ) received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks documents for the period January 1, 2000 through July 31, 2006, which is prior to Blackstone's acquisition by the Company. The Company believes that the subpoena concerns the compensation of physician consultants and related matters. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between the Company, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the Blackstone Merger Agreement ), for any losses to us resulting from this matter. (The Company's indemnification rights under the Blackstone Merger Agreement are described further below). The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

On or about January 7, 2008, the Company received a federal grand jury subpoena from the U.S. Attorney's Office for the District of Massachusetts. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On or about April 29, 2009, counsel for the Company received a HIPAA subpoena issued by the U.S. Department of Justice. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with

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

the Department of Health and Human Services, Office of Inspector General's investigation of such matters, as well as the January 7, 2008 federal grand jury subpoena. On or about April 23, 2010, counsel for Orthofix Inc. and Blackstone executed a tolling agreement with the U.S. Attorney's Office for the District of Massachusetts (the

**Table of Contents**

**ORTHOFIX INTERNATIONAL N.V.**

**NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Tolling Agreement ) that extends an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate to include the period from December 1, 2008 through and including June 30, 2010.

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

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

By order entered on January 4, 2007, the U.S. District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. The amended complaint in the Thomas action alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan and another provider. The Company believes that Blackstone has meritorious defenses to the claims alleged and the Company intends to defend vigorously against this lawsuit. On or about May 10, 2010 the Court granted the parties joint motion to stay all proceedings for six months. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have agreed to indemnify the Company for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders are limited to a cumulative aggregate amount of \$66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the

**Table of Contents**

**ORTHOFIX INTERNATIONAL N.V.**

**NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

escrow fund was \$50.0 million. As of June 30, 2010, the escrow fund, which has subsequently accrued interest, contained \$52 million. The Company is also entitled to seek direct personal recourse against certain principal shareholders of Blackstone after all monies on deposit in the escrow fund have been paid out or released or are the subject of pending or unresolved indemnification claims but only for a period of six years from the closing date of the merger and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

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

The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund and there can be no assurance that losses to the Company from these matters will not exceed the amount of the escrow fund. Expenses incurred by the Company relating to the above matters are recorded as an escrow receivable in the Company's financial statements to the extent the Company believes, among other things, that collection of the claims is reasonably assured. Expenditures related to such matters for which the Company believes collection is doubtful are recognized in earnings when incurred. As of June 30, 2010 and December 31, 2009, included in Other current assets is approximately \$14.4 million and \$12.9 million, respectively, of escrow receivable balances related to the Blackstone matters described above. These amounts include, among other things, attorneys' fees and costs related to the government investigations manifested by the subpoenas described above, the stock option-related claims described above, and costs related to the qui tam actions described above. As described above, these reimbursement claims are generally being contested by the representative of the former shareholders of Blackstone. To mitigate the risk that some reimbursement claims will not be collected, the Company records a reserve against the escrow receivable during the period in which reimbursement claims are recognized.

Effective October 29, 2007, Blackstone entered into a settlement agreement of a patent infringement lawsuit brought by certain affiliates of Medtronic Sofamor Danek USA Inc. In that lawsuit, the Medtronic plaintiffs had alleged that they were the exclusive licensees of certain U.S. patents and that Blackstone's making, selling, offering for sale, and using its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate, Reliant Cervical Plate, Pillar PEEK and Construx Mini PEEK VBR System products within the U.S. willfully infringed the subject patents. Blackstone denied infringement and asserted that the patents were invalid. The settlement agreement is not expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows. On July 20, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. The Company was subsequently notified by legal counsel of the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

On or about April 10, 2009, the Company received a HIPAA subpoena (HIPAA subpoena) issued by the U.S. Attorney's Office for the District of Massachusetts (the Boston USAO). The subpoena sought documents concerning, among other things, the Company's promotion and marketing of its bone growth stimulator devices. The Boston USAO issued supplemental subpoenas seeking documents in this matter, dated September 21, 2009 and December 16, 2009, respectively. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. Document production in response to the subpoenas is ongoing. The Boston USAO also issued two supplemental subpoenas requiring testimony in this matter dated July 23, 2009 and June 3, 2010. That office excused performance with the July 23, 2009 subpoena indefinitely. On December 21, 2009 and in July 2010, the Boston USAO provided the Company with grand jury subpoenas for the testimony of certain current employees in connection with its ongoing investigation. The Company intends to cooperate with the government's requests. In meetings with the Company and its attorneys regarding this matter, the Boston USAO has informed the Company that it is investigating possible criminal and civil violations of federal law related to the Company's promotion and marketing of its bone growth stimulator devices.

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the U.S. District Court for the District of Massachusetts against Orthofix, Inc., the Company, and other companies that have allegedly manufactured bone growth stimulation devices, including Orthologic Corp., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. By order entered on March 24, 2009, the court unsealed the case. The Company and Orthofix, Inc. were served on or about September 8, 2009. With leave of court, Relator's Second Amended Complaint was filed on June 11, 2010. The complaint alleges various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of bone growth stimulation devices. The complaint also includes claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-kickback Act by providing free products to physicians, waiving patients' insurance co-payments, and providing inducements to independent sales agents to generate business. The Company believes that this lawsuit is related to the matter described above involving the HIPAA subpoena. The Company intends to defend vigorously against this lawsuit.

On or about July 2, 2009, the Company obtained a copy of a qui tam complaint filed by Marcus Laughlin that is pending in the U.S. District Court for the District of Massachusetts against the Company. This complaint has been consolidated with the complaint described in the immediately preceding paragraph, and was unsealed on June 30, 2009. The Company was served with the complaint on or about September 9, 2009. With leave of Court, Relator filed a Second Amended Complaint on June 23, 2010. The complaint alleges violations of the federal False Claims Act and various state and local false claims acts, fraudulent billing, illegal kickbacks, conspiracy, and wrongful termination based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products, provided physicians kickbacks in the form of free units, referral fees, and fitting fees. The complaint also alleges that TRICARE has been reimbursing the Company for its Cervical Stim® product without approval to do so. The Company intends to defend vigorously against this lawsuit.

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

On April 22, 2010, the Company obtained a copy of a complaint filed by NuVasive, Inc. ( NuVasive ) and Osiris Therapeutics, Inc. ( Osiris ) in the U.S. District Court for the District of New Jersey against Orthofix International N.V., Orthofix, Inc., Orthofix Holdings, Inc., Orthofix Biologics, Orthofix Spinal Implants, and Musculoskeletal Transplant Foundation. The complaint alleges that the Company's Trinity® Evolution allograft product infringes a U.S. patent owned by Osiris and licensed to NuVasive. The complaint requests the court to enjoin the sale of Trinity® Evolution and award damages to NuVasive and Osiris for the alleged infringement. The Company was served with the complaint on April 28, 2010. On June 8, 2010 the Company filed an answer to the complaint and counterclaim seeking a declaratory judgment that the patent in question is invalid and not infringed. The Company believes that these defenses are meritorious and will continue to defend vigorously against the lawsuit.

During a recent internal management review of Promeca S.A. DE C.V. ( Promeca ), one of its Mexican subsidiaries, the Company received allegations of improper payments, allegedly made by certain of Promeca's local employees in Mexico, to employees of a Mexican governmental health care entity. The Company has engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation focusing on compliance with the Foreign Corrupt Practices Act ( FCPA ) and voluntarily contacted the U.S. Securities and Exchange Commission and the United States Department of Justice to advise both agencies that an internal investigation is underway. During 2009, Promeca accounted for approximately one percent of the Company's consolidated net sales and consolidated total assets. The internal investigation is in its early stages and no conclusions can be drawn at this time as to its outcome; however, the FCPA and related statutes and regulations provide for potential criminal and civil sanctions in connection with FCPA violations, including criminal fines, civil penalties, and disgorgement of past profits.

**Table of Contents**

**ORTHOFIX INTERNATIONAL N.V.**

**NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

In addition to the foregoing, in the normal course of our business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies. To the extent losses related to these contingencies are both probable and estimable, the Company provides appropriate amounts in the accompanying financial statements.



---

**Table of Contents**

**ORTHOFIX INTERNATIONAL N.V.**

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

The following discussion and analysis addresses our liquidity, financial condition, and the results of our operations for the three and six months ended June 30, 2010 compared to our results of operations for the three and six months ended June 30, 2009. These discussions should be read in conjunction with our historical consolidated financial statements and related notes thereto and the other financial information included in this Form 10-Q and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

***General Overview***

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

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

An increase in revenue driven by the introduction of a number of key new products that were launched in 2009, including the Trinity® Evolution allograft, the Firebird pedicle screw system, the PILLAR SA interbody device, and the Ascent® LE posterior cervical spine system.

An increase in gross profit margin driven by a full year of sales of our key new products indicated above, primarily Trinity® Evolution . While we record 70% of the sales price of Trinity® Evolution allograft versus recording 100% of the sales price of the old Trinity® product, we recognize a 100% gross profit margin from the marketing fees earned from the sales of this allograft, compared to approximately a 50% gross profit margin on our previous Trinity® product. This is due to the fact that we are not required to purchase inventory of Trinity® Evolution whereas, previously, we were required to purchase inventory of the old Trinity® product and record the associated cost of sales.

A decrease in operating expenses, as a percentage of revenue, as we continue to leverage our operating infrastructure against the increase in revenues noted above. In 2008, we initiated a reorganization and consolidation plan to reduce operating expenses by eliminating the redundancies and increasing operating efficiency. This plan included the consolidation of our Springfield, MA and Wayne, NJ locations into our operations in the Dallas, TX area. For a further discussion about this reorganization and consolidation plan, please refer to the explanation provided in our Liquidity and Capital Resources section of the Management Discussion and Analysis.

A continuation of strong financial performance from all of our segments.

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

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

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

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

**Table of Contents**

exchange prevailing during the period. Gains and losses resulting from foreign currency transactions are included in other income (expense), net on the statements of operations. Gains and losses resulting from the translation of foreign currency net assets are recorded in the accumulated other comprehensive income component of shareholders' equity.

Our financial condition, results of operations and cash flows are not significantly impacted by seasonality trends. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. Certain of the Breg bracing products experience greater demand in the fall and winter corresponding with high school and college football schedules and winter sports. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar denominated income and expenditures. During the six months ended June 30, 2010 and all of 2009, we have used derivative instruments to hedge foreign currency fluctuation exposures. See Item 3 Quantitative and Qualitative Disclosures About Market Risk.

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

*Segment and Market Sector Revenues*

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

**Business Segment:**

(US\$ in thousands)	2010		Three Months Ended June 30, 2009		Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	
Domestic	\$ 58,949	41%	\$ 53,635	39%	10%
Spinal Implants and Biologics	32,385	23%	30,025	22%	8%
Breg	22,197	16%	23,342	17%	-5%
International	29,314	20%	30,544	22%	-4%
<b>Total</b>	<b>\$ 142,845</b>	<b>100%</b>	<b>\$ 137,546</b>	<b>100%</b>	<b>4%</b>

(US\$ in thousands)	2010		Six Months Ended June 30, 2009		Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	
Domestic	\$ 114,335	40%	\$ 103,432	39%	11%
Spinal Implants and Biologics	61,711	22%	58,544	22%	5%
Breg	44,706	16%	46,452	17%	-4%
International	60,916	22%	58,092	22%	5%
<b>Total</b>	<b>\$ 281,668</b>	<b>100%</b>	<b>\$ 266,520</b>	<b>100%</b>	<b>6%</b>

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

(US\$ in thousands)	2010		Three Months Ended June 30, 2009		Reported Growth	Constant Currency Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales		
Spine	\$ 78,647	55%	\$ 70,732	51%	11%	11%
Orthopedics	36,641	26%	32,626	24%	12%	11%
Sports Medicine	23,130	16%	24,460	18%	-5%	-5%
Other	4,427	3%	9,728	7%	-54%	-55%
<b>Total</b>	<b>\$ 142,845</b>	<b>100%</b>	<b>\$ 137,546</b>	<b>100%</b>	<b>4%</b>	<b>4%</b>

(US\$ in thousands)	2010		Six Months Ended June 30, 2009		Reported Growth	Constant Currency Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales		
Spine	\$ 150,328	53%	\$ 136,860	52%	10%	10%
Orthopedics	72,903	26%	62,219	23%	17%	13%
Sports Medicine	46,720	17%	48,706	18%	-4%	-4%
Other	11,717	4%	18,735	7%	-37%	-40%
<b>Total</b>	<b>\$ 281,668</b>	<b>100%</b>	<b>\$ 266,520</b>	<b>100%</b>	<b>6%</b>	<b>5%</b>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010 (%)	2009 (%)	2010 (%)	2009 (%)
Net sales	100	100	100	100
Cost of sales	24	27	24	26
Gross profit	76	73	76	74
Operating expenses				
Sales and marketing	40	40	40	40
General and administrative	14	15	15	17
Research and development	6	7	6	7
Amortization of intangible assets	1	1	1	1
Loss (gain) on sale of vascular operations			(5)	
Total operating income	15	10	19	9
Net income	7	4	10	3

**Table of Contents****Three Months Ended June 30, 2010 Compared to Three Months Ended June 30, 2009**

Net sales increased 4% to \$142.8 million in the second quarter of 2010 compared to \$137.5 million for the same period last year. The impact of foreign currency increased sales by \$0.4 million during the second quarter of 2010 when compared to the second quarter of 2009.

*Sales by Business Segment:*

Net sales in Domestic increased to \$58.9 million in the second quarter of 2010 compared to \$53.6 million for the same period last year, an increase of 10%. Domestic's net sales represented 41% and 39% of total net sales during the second quarter of 2010 and 2009, respectively. The increase in Domestic's net sales was primarily the result of a 12% increase in sales in our Spine market sector, which was mainly driven by increased sales of our Spinal-Stim® and Cervical-Stim® products, both which increased 13% and 11%, respectively, when compared to the same period in the prior year. The increase in Domestic's net sales was also attributable to a 4% increase in our Orthopedics market sector which included a 7% increase in sales of our external fixation products, a 5% increase in our HCT/P products, specifically Trinity® Evolution, and a 4% increase in sales of our Physio-Stim® products.

*Domestic Sales by Market Sector:*

(US\$ in thousands)	Net Sales for the Three Months Ended June 30,		Growth
	2010	2009	
Spine	\$ 44,951	\$ 40,142	12%
Orthopedics	13,998	13,493	4%
<b>Total</b>	<b>\$ 58,949</b>	<b>\$ 53,635</b>	<b>10%</b>

Net sales in Spinal Implants and Biologics increased \$2.4 million to \$32.4 million in the second quarter of 2010 compared to \$30.0 million for the same period last year, an increase of 8%. Spinal Implants and Biologics' net sales represented 23% and 22% of total net sales during the second quarter of 2010 and 2009, respectively. The increase in sales was primarily related to an 18% increase in our thoracolumbar products due to the introduction of the Firebird pedicle screw system which was introduced during the second quarter of 2009. Sales of our interbody products increased by 18%, when compared to the same period in the prior year, as a result of the introduction of the Pillar SA interbody device which was introduced during the third quarter of 2009. These sales increases were partially offset by a 16% sales decrease in our biologics products when compared to the same period last year primarily due to the impact of the transition to recording a marketing fee for Trinity® Evolution versus previously recording full end user sales for the Company's prior stem cell-based allograft. Full market release of our Trinity® Evolution stem cell-based allograft occurred on July 1, 2009. All of Spinal Implants and Biologics' sales are recorded in our Spine market sector.

Net sales in Breg decreased \$1.1 million to \$22.2 million in the second quarter of 2010 compared to \$23.3 million for the same period last year, a decrease of 5%. Breg's net sales represented 16% and 17% of total net sales during the second quarter of 2010 and 2009, respectively. The decrease in net sales includes the impact of a revenue reclassification where commissions for a certain distributor are now netted against the gross revenue. Excluding the impact of this change, net sales in Breg for the second quarter of 2010 would have decreased by 3% when compared with the same period in the prior year. The decrease in Breg's net sales was primarily due to a 4% reduction in sales of our Breg bracing products and a 3% decrease in our cold therapy products when compared to the same period in the prior year. We continue to see a trend where the number of elective surgeries is declining. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International decreased 4% to \$29.3 million in the second quarter of 2010 compared to \$30.5 million for the same period last year. International's net sales represented 20% and 22% of our total net sales in the second quarter of 2010 and 2009, respectively. The decrease in International's net sales was primarily due to reduced sales in our other distributed products which decreased to \$4.4 million in the second quarter of 2010 compared to \$9.7 million in the same period for the prior year. During the first quarter of 2010, we disposed of our

**Table of Contents**

vascular operations. (See Loss (Gain) on Sale of Vascular Operations further below). In June 2010, we transitioned out of our agreement to distribute the Laryngeal Mask product in the United Kingdom. In October 2009, we transitioned out of our agreement to distribute the Laryngeal Mask product in Italy. The sales decreases in our other distributed products were partially offset by an increase in our Orthopedics sector which increased to \$22.6 million in the second quarter of 2010 compared to \$19.1 million in the same period of the prior year. The impact of foreign currency increased International net sales by 1% or \$0.4 million, during the second quarter of 2010 as compared to the second quarter of 2009, principally due to the strengthening of certain currencies outside of Europe, offset by the weakening of the Euro against the U.S. dollar. On a constant currency basis, sales for the Orthopedics sector increased 17% in the second quarter of 2010 when compared to the prior year. Within the Orthopedics sector, external fixation, internal fixation and deformity correction increased 12%, 2% and 24%, respectively, on a constant currency basis, when compared with the same period last year.

**International Sales by Market Sector:**

(US\$ in thousands)	Net Sales for the Three Months Ended June 30,		Reported Growth	Constant Currency Growth
	2010	2009		
Spine	\$ 1,311	\$ 565	132%	132%
Orthopedics	22,643	19,133	18%	17%
Sports Medicine	933	1,118	-17%	-15%
Other	4,427	9,728	-54%	-55%
<b>Total</b>	<b>\$ 29,314</b>	<b>\$ 30,544</b>	<b>-4%</b>	<b>-5%</b>

**Sales by Market Sector:**

Sales of our Spine products increased to \$78.6 million in the second quarter of 2010 compared to \$70.7 million in the second quarter of 2009. Sales of our Cervical-Stim® and Spinal-Stim® products increased 11% and 13%, respectively, in the second quarter of 2010 compared to 2009. In addition, sales of our Spinal Implants and Biologics products increased 8% over the same period in the prior year due to the introduction of new thoracolumbar products, previously discussed, as well as increased sales of our interbody and cervical products. Spine product sales were 55% and 51% of our total net sales in the second quarter of 2010 and 2009, respectively.

Sales of our Orthopedics products increased \$4.0 million to \$36.6 million in the second quarter of 2010 compared to \$32.6 million for the same period last year. Sales increased 12% compared to the same period last year due to increased sales of our internal fixation, external fixation, deformity correction and HCT/P products. Orthopedic product sales were 26% and 24% of our total net sales in the second quarter of 2010 and 2009, respectively.

Sales of our Sports Medicine products decreased 5% to \$23.1 million in the second quarter of 2010 compared to \$24.5 million for the same period last year. As discussed above, net sales would have decreased by 4% when comparing the second quarter of 2010 to the same period in the prior year, had it not been for a reclassification of certain commissions which are reflected as a reduction of gross revenue, but were originally recorded in operating expenses. The decrease in the sales of our Sports Medicine products was primarily due to a 4% reduction in sales of our bracing products and a 3% decrease in our cold therapy products when compared to the same period in the prior year. Sports Medicine product sales were 16% and 18% of our total net sales in the second quarter of 2010 and 2009, respectively.

Sales of our Other products which includes our Laryngeal Mask product, our Woman's Care line, and our former Vascular line decreased 54% to \$4.4 million in the second quarter of 2010 compared to \$9.7 million for the

**Table of Contents**

same period last year. During the first quarter of 2010, we disposed of our vascular operations. (See Loss (Gain) on Sale of Vascular Operations further below). In June 2010, we transitioned out of our agreement to distribute the Laryngeal Mask product in the United Kingdom. In October 2009, we transitioned out of our agreement to distribute the Laryngeal Mask product in Italy. Other product sales were 3% and 7% of our total net sales in the second quarter of 2010 and 2009, respectively.

*Gross Profit* Our gross profit increased 8% to \$108.8 million in the second quarter of 2010, compared to \$100.6 million for the same period last year. Gross profit, as a percent of net sales, in the second quarter of 2010 was 76.1% compared to 73.2% for the same period last year. The gross margin in the second quarter of 2009 included the impact of a \$1.8 million increase in our inventory reserves, which related primarily to the supply of Trinity® allograft remaining on hand at the expiration of the Company's distribution agreement on June 30, 2009. Excluding the impact of this adjustment, gross profit, as a percent of net sales, in the second quarter of 2009 would have been 74.5%. The increase in the gross profit is primarily due to the increased sales of higher margin stimulation products and Spinal Implants and Biologics products. As mentioned previously, while we record 70% of the sales price of Trinity® Evolution allograft versus recording 100% of the sales price of the old Trinity® product, we recognize a 100% gross profit margin from the marketing fees earned from the sales of this allograft, compared to an approximately 50% gross profit margin on our previous Trinity® product. This is due to the fact that we are not required to purchase inventory of Trinity® Evolution whereas, previously, we were required to purchase inventory of the old Trinity® product and record the associated cost of sales.

*Sales and Marketing Expense* Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$1.9 million, or 3%, to \$57.2 million in the second quarter of 2010 compared to \$55.3 million in the second quarter of 2009. As a percent of net sales, sales and marketing expense was 40.0% and 40.2% in the second quarter of 2010 and 2009, respectively.

*General and Administrative Expense* General and administrative expense decreased \$0.8 million, or 4%, in the second quarter of 2010 to \$20.4 million compared to \$21.2 million in the second quarter of 2009. The decrease is primarily due to a restructuring charge recorded in the second quarter of 2009 to consolidate substantially all of Spinal Implants and Biologics operations previously conducted in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and U.S. orthopedics business in the Dallas, TX area. General and administrative expense, as a percent of net sales, was 14.3% in the second quarter of 2010 compared to 15.4% for the same period last year.

*Research and Development Expense* Research and development expense decreased \$0.5 million in the second quarter of 2010 to \$8.4 million compared to \$8.9 million for the same period last year. During the second quarter of 2010, we incurred \$1.6 million in expenses related to research and development projects associated with our orthopedics and long bone stimulation devices. During the second quarter of 2009, we incurred \$2.1 million in expenses from our collaborative arrangement with the Musculoskeletal Transplant Foundation ( MTF ). As a percent of sales, research and development expense was 5.9% in the second quarter of 2010 compared to 6.5% for the same period last year.

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

*Loss (Gain) on Sale of Vascular Operations* As previously announced in the first quarter of 2010, the Company recorded a gain on the sale of its vascular operations related to the A-V IMPULSE SYSTEM® and related accessories on March 8, 2010. During the second quarter of 2010, the Company recorded additional transaction related expenses of \$0.2 million due to a revision in its estimated costs that were previously disclosed.

*Interest Expense, net* Interest expense, net was \$5.4 million for the second quarter of 2010 compared to \$5.8 million for the same period last year. The decrease was primarily the result of a lower year-over-year outstanding debt balance, partially offset by a higher rate of effective interest.

*Gain on Interest Rate Swap* In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the Swap ) with a notional amount of \$150.0 million and an expiration date of June 30, 2011.

**Table of Contents**

During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's amended credit facility, the Swap was no longer deemed highly effective. Special hedge accounting was no longer applied and fair value adjustments were reported in current earnings. On June 29, 2010, the Company settled the Swap with the financial institution holder of the derivative instrument. For the second quarter ended 2010 and 2009, the Company recorded a gain of \$0.9 million and \$1.0 million, respectively, related to the change in the fair value of the Swap.

*Other Income (Expense), net* Other income (expense), net reflected income of \$0.1 million for the second quarter of 2010 compared to income of \$0.4 million for the same period last year. These charges are mainly related to foreign exchange. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies.

*Income Tax Expense* Our effective tax rate as a percentage of income was 39.0% and 35.9% during the second quarters of 2010 and 2009, respectively. The effective tax rate for the second quarter of 2010 was affected by the mix of earnings among various tax jurisdictions and losses incurred in a number of foreign jurisdictions, for which the Company does not currently recognize a tax benefit. The Company does not believe that it is more likely than not that it will generate sufficient future income in these jurisdictions to allow for the utilization of these losses before their expiration.

*Net Income* Net income for the second quarter of 2010 was \$10.2 million, or \$0.58 per basic share and \$0.57 per diluted share, compared to a net income of \$5.9 million, or \$0.35 per basic share and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,579,221 and 17,107,084 during the second quarters of 2010 and 2009, respectively. The weighted average number of diluted common shares outstanding was 17,892,886 and 17,172,557 during the second quarters of 2010 and 2009, respectively.

**Six Months Ended June 30, 2010 Compared to Six Months Ended June 30, 2009**

Net sales increased 6% to \$281.7 million for the first six months of 2010 compared to \$266.5 million for the same period last year. The impact of foreign currency increased sales by \$3.0 million for the first six months of 2010 when compared to the first six months of 2009.

**Sales by Business Segment:**

Net sales in Domestic increased to \$114.3 million in the first six months of 2010 compared to \$103.4 million for the same period last year, an increase of 11%. Domestic's net sales represented 40% and 39% of total net sales during the second quarter of 2010 and 2009, respectively. The increase in Domestic's net sales was primarily the result of a 12% increase in sales in our Spine market sector, which was mainly driven by increased sales of our Spinal-Stim® and Cervical-Stim® products, both which increased 13% and 12%, respectively, when compared to the same period in the prior year. The increase in Domestic's net sales was also attributable to a 6% increase in our Orthopedics market sector which included an 11% increase in sales of our external fixation products, a 14% increase in our HCT/P products, specifically Trinity® Evolution, and a 3% increase in sales of our Physio-Stim® products.

**Domestic Sales by Market Sector:**

(US\$ in thousands)	Net Sales for the		
	Six Months Ended June 30,		Growth
	2010	2009	
Spine	\$ 86,861	\$ 77,425	12%
Orthopedics	27,474	26,007	6%
Total	\$ 114,335	\$ 103,432	11%



**Table of Contents**

Net sales in Spinal Implants and Biologics increased \$3.2 million to \$61.7 million in the first six months of 2010 compared to \$58.5 million for the same period last year, an increase of 5%. Spinal Implants and Biologics' net sales represented 22% of total net sales during both of the first six months of 2010 and 2009. The increase in sales was primarily related to a 16% increase in our thoracolumbar products due to the introduction of the Firebird pedicle screw system which was introduced during the second quarter of 2009. Sales of our interbody products increased by 22%, when compared to the same period in the prior year, as a result of the introduction of the Pillar SA interbody device which was introduced during the third quarter of 2009. These sales increases were partially offset by a 21% sales decrease in our biologics products when compared to the same period last year primarily due to the impact of the transition to recording a marketing fee for Trinity® Evolution versus previously recording full end user sales for the Company's prior stem cell-based allograft. Full market release of our Trinity® Evolution stem cell-based allograft occurred on July 1, 2009. All of Spinal Implants and Biologics' sales are recorded in our Spine market sector.

Net sales in Breg decreased \$1.7 million to \$44.7 million in the first six months of 2010 compared to \$46.5 million for the same period last year, a decrease of 4%. Breg's net sales represented 16% and 17% of total net sales during the first six months of 2010 and 2009, respectively. The decrease in net sales includes the impact of a revenue reclassification where commissions for a certain distributor are now netted against the gross revenue. Excluding the impact of this change, net sales in Breg for the first six months of 2010 would have decreased by 2% when compared with the same period in the prior year. The decrease in Breg's net sales was primarily due to a 4% reduction in sales of our Breg bracing products when compared to the same period in the prior year. We continue to see a trend where the number of elective surgeries is declining. Sales of our cold therapy products remained relatively flat compared to the same period in the prior year. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International increased 5% to \$60.9 million in the first six months of 2010 compared to \$58.1 million for the same period last year. International's net sales represented 22% of our total net sales in both the first six months of 2010 and 2009. The impact of foreign currency increased International net sales by 5%, or \$3.0 million, during the first six months of 2010 as compared to the same period last year, principally due to the strengthening of certain currencies outside of Europe, offset by the weakening of the Euro against the U.S. dollar. On a constant currency basis, sales for the Orthopedics sector increased 19% in the first six months of 2010 when compared to the prior year. Within the Orthopedics sector, external fixation, internal fixation and deformity correction increased 17%, 15% and 34%, respectively, on a constant currency basis, when compared with the same period last year. Partially offsetting these sales increases was a reduction of sales in our other distributed products. Other distributed products decreased to \$11.7 million for the first six months of 2010 compared to \$18.7 million for the first six months of 2009. During the first quarter of 2010, we disposed of our vascular operations. (See Loss (Gain) on Sale of Vascular Operations further below). In June 2010, we transitioned out of our agreement to distribute the Laryngeal Mask product in the United Kingdom. In October 2009, we transitioned out of our agreement to distribute the Laryngeal Mask product in Italy.

**International Sales by Market Sector:**

(US\$ in thousands)	Net Sales for the Six Months Ended June 30,		Reported Growth	Constant Currency Growth
	2010	2009		
Spine	\$ 1,756	\$ 891	97%	97%
Orthopedics	45,429	36,212	25%	19%
Sports Medicine	2,014	2,254	-11%	-13%
Other	11,717	18,735	-37%	-40%
<b>Total</b>	<b>\$ 60,916</b>	<b>\$ 58,092</b>	<b>5%</b>	<b>0%</b>

**Table of Contents***Sales by Market Sector:*

Sales of our Spine products increased to \$150.3 million in the first six months of 2010 compared to \$136.9 million in the first six months of 2009. Sales of our Cervical-Stim® and Spinal-Stim® products increased 12% and 13%, respectively, in the first six months of 2010 compared to 2009. In addition, sales of our Spinal Implants and Biologics products increased 6% over the same period in the prior year due to the introduction of new thoracolumbar products, previously discussed, as well as increased sales of our interbody and cervical products. Spine product sales were 53% and 52% of our total net sales in the first six months of 2010 and 2009, respectively.

Sales of our Orthopedics products increased \$10.7 million, or 17%, to \$72.9 million in the first six months of 2010 compared to \$62.2 million for the same period last year due to increased sales of our internal fixation, external fixation, deformity correction and HCT/P products. Orthopedic product sales were 26% and 23% of our total net sales in the first six months of 2010 and 2009, respectively.

Sales of our Sports Medicine products decreased 4% to \$46.7 million in the first six months of 2010 compared to \$48.7 million for the same period last year. As discussed above, net sales would have decreased by 2% when comparing the first six months of 2010 to the same period in the prior year, had it not been for a reclassification of certain commissions which are reflected as a reduction of gross revenue, but were originally recorded in operating expenses. The decrease in the sales of our Sports Medicine products was primarily due to a 4% reduction in sales of our bracing products when compared to the same period in the prior year. Sports Medicine product sales were 17% and 18% of our total net sales in the first six months of 2010 and 2009, respectively.

Sales of our Other products, which includes our Laryngeal Mask product, our Woman's Care line, and our former Vascular line decreased 37% to \$11.7 million in the first six months of 2010 compared to \$18.7 million for the same period last year. During the first quarter of 2010, we disposed of our vascular operations. (See Loss (Gain) on Sale of Vascular Operations further below). In June 2010, we transitioned out of our agreement to distribute the Laryngeal Mask product in the United Kingdom. In October 2009, we transitioned out of our agreement to distribute the Laryngeal Mask product in Italy. Other product sales were 4% and 7% of our total net sales in the first six months of 2010 and 2009, respectively.

*Gross Profit* Our gross profit increased 9% to \$214.9 million in the first six months of 2010, compared to \$196.8 million for the same period last year. Gross profit, as a percent of net sales, in the first six months of 2010 was 76.3% compared to 73.8% for the same period last year. The gross profit in the first six months of 2010 also includes the impact of a \$1.9 million increase in the provision for inventory obsolescence recorded in connection with the discontinued U.S. Advent Cervical disc clinical trial. The gross profit in the first six months of 2009 included the impact of a \$1.8 million increase in our inventory reserves, which related primarily to the supply of Trinity® allograft remaining on hand at the expiration of the Company's distribution agreement on June 30, 2009. Excluding the impact of these adjustments, gross profit, as a percent of net sales, in the first six months of 2010 and 2009 would have been 77.0% and 74.5%, respectively. The increase in the gross profit is primarily due to the increased sales of higher margin stimulation products and Spinal Implants and Biologics products. As mentioned previously, while we record 70% of the sales price of Trinity® Evolution allograft versus recording 100% of the sales price of the old Trinity® product, we recognize a 100% gross profit margin from the marketing fees earned from the sales of this allograft, compared to an approximately 50% gross profit margin on our previous Trinity® product. This is due to the fact that we are not required to purchase inventory of Trinity® Evolution whereas, previously, we were required to purchase inventory of the old Trinity® product and record the associated cost of sales.

*Sales and Marketing Expense* Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$5.9 million, or 6%, to \$113.5 million in the first six months of 2010 compared to \$107.5 million in the first six months of 2009. As a percent of net sales, sales and marketing expense was 40.3% and 40.4% in the first six months of 2010 and 2009, respectively.

*General and Administrative Expense* General and administrative expense decreased \$2.0 million, or 5%, in the first six months of 2010 to \$41.8 million compared to \$43.9 million in the first six months of 2009. The decrease is primarily due to a restructuring charge recorded in the first six months of 2009 to consolidate

**Table of Contents**

substantially all of Spinal Implants and Biologics operations previously conducted in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and U.S. orthopedics business in the Dallas, TX area. In addition, during the first quarter of 2009, the Company incurred \$0.7 million of costs incurred in connection with a proxy contest. General and administrative expense, as a percent of net sales, was 14.9% in the first six months of 2010 compared to 16.5% for the same period last year.

*Research and Development Expense* Research and development expense decreased \$2.1 million in the first six months of 2010 to \$16.0 million compared to \$18.0 million for the same period last year. During the first six months of 2010, we incurred \$2.9 million in expenses related to research and development projects associated with our orthopedics and long bone stimulation devices. During the first six months of 2009, we incurred \$3.9 million and \$1.0 million in expenses primarily related to collaborative arrangements with MTF and Intelligent Implant Systems, LLC ( IIS ), respectively. As a percent of sales, research and development expense was 5.6% in the first six months of 2010 compared to 6.7% for the same period last year.

*Amortization of Intangible Assets* Amortization of intangible assets decreased \$0.4 million in the first six months of 2010 to \$2.9 million compared to \$3.3 million for the same period last year.

*Loss (Gain) on Sale of Vascular Operations* The gain on sale of Vascular Operations was \$12.3 million in the first six months of 2010 and represented the gain on the sale of our vascular operations related to the A-V IMPULSE SYSTEM® and related accessories on March 8, 2010. No such gain was recorded in the first six months of 2009.

*Interest Expense, net* Interest expense, net was \$11.3 million for the first six months of 2010 compared to \$11.9 million for the same period last year, primarily the result of a lower year-over-year outstanding debt balance, partially offset by a higher rate of effective interest.

*Gain on Interest Rate Swap* In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the Swap ) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's amended credit facility, the Swap was no longer deemed highly effective. Special hedge accounting was no longer applied and fair value adjustments were reported in current earnings. On June 29, 2010, the Company settled the Swap with the financial institution holder of the derivative instrument. The Company recorded a gain of \$1.3 million in both the first six months of 2010 and 2009 related to the change in the fair value of the Swap.

*Other Income (Expense), net* Other income (expense), net reflected an expense of \$(0.2) million for the first six months of 2010 compared to income of \$0.1 million for the same period last year. These charges are mainly related to foreign exchange. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies.

*Income Tax Expense* Our effective tax rate as a percentage of income was 35.4% and 35.0% for the six months ended June 30, 2010 and 2009, respectively. The effective tax rate for the first six months of 2010 was affected by the gain on the sale of vascular operations and the mix of earnings among various tax jurisdictions. Without the sale of the vascular operations, the Company's tax rate would have been approximately 38.4%. The Company also incurs losses in a number of foreign jurisdictions for which the Company does not currently recognize a tax benefit. The Company does not believe that it is more likely than not that it will generate sufficient future income in these jurisdictions to allow for the utilization of these losses before their expiration.

*Net Income* Net income for the first six months of 2010 was \$27.7 million, or \$1.58 per basic share and \$1.56 per diluted share, compared to net income of \$8.8 million, or \$0.52 per basic share and \$0.51 per diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,534,456 and 17,105,323 during the first six months of 2010 and 2009, respectively. The weighted average number of diluted common shares outstanding was 17,825,604 and 17,139,789 during the first six months of 2010 and 2009, respectively.

**Table of Contents*****Liquidity and Capital Resources***

Cash and cash equivalents at June 30, 2010 were \$39.0 million, of which \$19.3 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$25.0 million at December 31, 2009, of which \$11.6 million was restricted.

Net cash provided by operating activities was \$11.8 million for the six months ended June 30, 2010 compared to net cash provided by operating activities of \$17.0 million for the same period last year. Net cash provided by operating activities is comprised of net income, non-cash items (including depreciation and amortization, share-based compensation, provision for doubtful accounts, provision for inventory obsolescence, deferred taxes, and gain on sale of vascular operations) and changes in working capital, including changes in restricted cash. Net income increased \$18.9 million to \$27.7 million for the six months ended June 30, 2010 from net income of \$8.8 million for the comparable period in the prior year. Non-cash expense for the six months ended June 30, 2010 decreased \$14.2 million compared to the same period last year primarily as a result of the gain on the sale of vascular operations of \$12.3 million and a decrease in inventory obsolescence of \$1.1 million. Working capital accounts consumed \$24.5 million of cash in the six months ended June 30, 2010 compared to \$14.6 million for the same period last year. The higher consumption of working capital in the 2010 period can be attributed to decreases in the change in restricted cash of \$3.2 million and other current liabilities of \$16.7 million, which includes the effect on cash of \$4.8 million to settle our interest rate swap. This was partially offset by increases in the change in inventory of \$6.5 million and trade accounts payable of \$3.5 million. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 82 days at June 30, 2010 compared to 79 days at June 30, 2009 and inventory turns of 1.6 times for both June 30, 2010 and June 30, 2009.

Net cash provided by investing activities was \$12.3 million during the six months ended June 30, 2010 compared to net cash used in investing activities of \$9.2 million during the same period last year. During the first quarter of 2010, we sold our vascular operations with cash proceeds, net of litigation, of \$24.2 million. During the six months ended June 30, 2010 and 2009, we invested \$11.9 million and \$9.2 million in capital expenditures, respectively.

Net cash used in financing activities was \$16.8 million for the six months ended June 30, 2010 compared to \$16.6 million for the same period last year. During the six months ended June 30, 2010, we repaid approximately \$25.7 million against the principal on our senior secured term loan compared to \$16.6 million during the six months ended June 30, 2009. During the six months ended June 30, 2010, we received proceeds of \$6.0 million from the issuance of 478,528 shares of our common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

On September 22, 2006 the Company's wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. ( Orthofix Holdings ), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone Medical Inc. ( Blackstone ). Certain terms of the senior secured credit facility were amended on September 29, 2008 and February 24, 2010. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million and (2) a six-year revolving credit facility of \$45.0 million. As of June 30, 2010, the Company had \$0.3 million of letters of credit outstanding under the revolving credit facility and \$226.8 million outstanding under the term loan facility. Obligations under the senior secured credit facility can have a floating interest rate of the London Inter-Bank Offered Rate ( LIBOR ) plus a margin, with a LIBOR floor of 3.0%, or prime rate plus a margin. As of June 30, 2010, the entire term loan obligation of \$226.8 million is at the prime rate plus a margin of 3.50%. The effective interest rates on the senior secured credit facility as of June 30, 2010 and December 31, 2009 were 9.0% and 8.8%, respectively. Excluding the interest rate swap, the effective interest rate as of June 30, 2010 and December 31, 2009 would have been 6.75% and 7.1% respectively.

The Company made a mandatory payment on its principal balance amounting to \$19.0 million on March 31, 2010. This principal payment represented all of the preliminary net proceeds the Company received on the sale of its vascular operations on March 8, 2010 (see Note 18 to the Condensed Consolidated Financial Statements). In addition, the Company made voluntary advance payments of principal of \$5.0 million and \$15.0 million during the six months ended June 30, 2010 and 2009, respectively.

**Table of Contents**

The credit agreement contains certain financial covenants, including a fixed charge coverage ratio and a leverage ratio, applicable to Orthofix and its subsidiaries on a consolidated basis. A breach of any of these covenants could result in an event of default under the credit agreement, which could permit acceleration of the debt payments under the facility. The Company was in compliance with these financial covenants as measured at June 30, 2010. As defined in the senior secured credit facility, our leverage ratio can not exceed 2.75 and our fixed charge ratio must be greater than or equal to 1.375. At June 30, 2010, our leverage and fixed charge ratios were 1.89 and 1.61, respectively.

As defined in the senior secured credit facility, the leverage ratio the Company cannot exceed is 2.75 for the second quarter of 2010 and 2.50 thereafter. The fixed charge coverage ratio must be greater than 1.375 and remain at that rate for the remaining life of the senior secured credit facility. Based on the Company's projected earnings, we believe that the Company should be able to meet these financial covenants in future fiscal quarters, however, there can be no assurance that it will be able to do so, and failure to do so could result in an event of default under the credit agreement, which could have a material adverse effect on our financial position.

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

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's senior secured credit facility. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of June 30, 2010 is \$152.3 million compared to \$143.0 million at December 31, 2009. In addition, the senior secured credit facility restricts the Company and subsidiaries that are not parties to the credit facility from access to cash held by Colgate Medical Limited and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of June 30, 2010 is \$19.3 million compared to \$11.6 million at December 31, 2009.

At June 30, 2010, we had outstanding borrowings of \$2.8 million and unused available lines of credit of approximately 5.0 million Euro (\$6.1 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

We believe that current cash balances together with projected cash flows from operating activities, the availability of the \$44.7 million revolving credit facility, the available Italian line of credit, and our debt capacity are sufficient to cover anticipated working capital and capital expenditure needs including research and development costs and research and development projects formerly mentioned, over the near term.

In the fourth quarter of 2008, as part of the Company's strategic plan to strengthen the business, the Company initiated a restructuring plan to improve operations and reduce costs at Blackstone. The plan involved the consolidation of substantially all of Spinal Implants and Biologics operations previously conducted in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and U.S. orthopedics business in the Dallas, TX area. The Company plans to complete the restructuring and consolidation during the third quarter of 2010, at which time the Company anticipates a total restructuring expense of \$3.6 million. During the three and six months ended June 30, 2010, the Company did not record any restructuring charges.

The following table presents changes in the restructuring liability for the activity discussed above, which is included within Other Current Liabilities in the Company's consolidated balance sheets as of June 30, 2010 and December 31, 2009:

(US\$ in thousands)	Severance	Assets Abandoned	Total
Balance at December 31, 2009	\$ 1,826	\$	\$ 1,826
Charges			
Cash Payments	(1,807)		(1,807)
Non-cash Items			
Balance at June 30, 2010	\$ 19	\$	\$ 19



**Table of Contents**

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

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

Pursuant to the APA, the Orthofix Parties agreed to enter into certain transition arrangements at the closing under the APA, including (i) a transition services agreement with the Covidien Parties pursuant to which, among other things, the Orthofix Parties will continue to provide operational support with respect to the transferred assets in certain jurisdictions for a period of up to five months, and (ii) two separate supply agreements with certain of the Covidien Parties pursuant to which, among other things, certain of the Orthofix Parties will provide manufacturing and logistics services on behalf of Covidien with respect to certain ImPads for a period of two years and provide other products for a period of 90 days. During the second quarter of 2010, the Company completed the transition services agreement with the Covidien parties and they agreed to extend one of the supply agreements (which supplies the other products) by an additional 90 days. The Orthofix Parties also agreed to enter into a 5-year noncompetition agreement at closing with respect to the business of the assets being transferred.

The following table presents the value of the asset disposition, including the cash purchase price, cash proceeds received, net of litigation costs and gain on the sale of the vascular operations as shown in the Condensed Consolidated Statements of Operations for the six months ended June 30, 2010.

(US\$ in thousands)	Total
Gross cash proceeds received from sale of vascular operations	\$ 27,701
Litigation settlement <sup>(1)</sup>	3,486
Cash proceeds, net of litigation	24,215
Less:	
Transaction related expenses	1,933
Inventory	1,570
Tangible assets	799
Identifiable intangible assets	543
Goodwill	7,031
Pre-tax gain on sale of vascular operations	12,339
Income tax expense	3,498
Net gain on sale of vascular operations	\$ 8,841

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

---

**Table of Contents**

**ORTHOFIX INTERNATIONAL N.V.**

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations, and the cost of financing and yields on cash and short-term investments. We use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of June 30, 2010, we had a cross-currency swap in place to minimize foreign currency exchange risk related to a 38.3 million Euro intercompany note.

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

As of June 30, 2010, we had \$226.8 million of variable rate term debt represented by borrowings under our senior secured term loan which can have a floating interest rate of LIBOR plus a margin, with a LIBOR floor of 3.0%, or the prime rate plus a margin. As of June 30, 2010, the entire term loan obligation of \$226.8 million is at the prime rate plus a margin of 3.50%, which is adjusted based upon the credit rating of the Company and its subsidiaries. As of June 30, 2010, our effective interest rate on our senior secured debt was 9.0%. Based on the balance outstanding under the senior secured term loan as of June 30, 2010, an immediate change of one percentage point in the applicable interest rate on the variable rate debt would cause a change in interest expense of approximately \$0.6 million on a quarterly basis and \$2.3 million annually.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Great Britain Pound, Mexican Peso and Brazilian Real. We are subject to cost of goods currency exposure when we produce products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. As of June 30, 2010, we had an un-hedged intercompany balance denominated in Euro of approximately 22.1 million (\$27.1 million). We recorded a foreign currency loss during the six months ended June 30, 2010 of \$4.5 million, which resulted from the weakening of the Euro against the U.S. dollar during the period.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the six months ended June 30, 2010 by foreign currency exchange rate fluctuations with the weakening of the U.S. dollar against the local foreign currency during this period in certain countries outside of Europe, partially offset by the effect of the strengthening of the U.S. dollar against the Euro. The U.S. dollar equivalent of international sales denominated in foreign currencies was unfavorably impacted during the six months ended June 30, 2009 by foreign currency exchange rate fluctuations with the strengthening of the U.S. dollar against most local foreign currencies during this period. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results.



**Table of Contents**

**ORTHOFIX INTERNATIONAL N.V.**

**Item 4. Controls and Procedures**

***Disclosure Controls and Procedures***

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

***Changes in Internal Control over Financial Reporting***

There have not been any changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2010 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****PART II. OTHER INFORMATION****Item 1. Legal Proceedings**

On or about July 23, 2007, our subsidiary, Blackstone Medical Inc. ( Blackstone ) received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks documents for the period January 1, 2000 through July 31, 2006, which is prior to Blackstone's acquisition by the Company. The Company believes that the subpoena concerns the compensation of physician consultants and related matters. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between the Company, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the Blackstone Merger Agreement ), for any losses to us resulting from this matter. (The Company's indemnification rights under the Blackstone Merger Agreement are described further below). The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

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

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

**Table of Contents**

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

By order entered on January 4, 2007, the U.S. District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. The amended complaint in the Thomas action alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan and another provider. The Company believes that Blackstone has meritorious defenses to the claims alleged and the Company intends to defend vigorously against this lawsuit. On or about May 10, 2010 the Court granted the parties joint motion to stay all proceedings for six months. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have agreed to indemnify the Company for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders are limited to a cumulative aggregate amount of \$66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was \$50.0 million. As of June 30, 2010, the escrow fund, which has subsequently accrued interest, contained \$52 million. The Company is also entitled to seek direct personal recourse against certain principal shareholders of Blackstone after all monies on deposit in the escrow fund have been paid out or released or are the subject of pending or unresolved indemnification claims but only for a period of six years from the closing date of the merger and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

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

The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund and there can be no assurance that losses to the Company from these matters will not exceed the amount of the escrow fund. Expenses incurred by the Company relating to the above matters are recorded as an escrow receivable in the Company's financial statements to the extent the Company believes, among other things, that collection of the claims is reasonably assured. Expenditures related to such matters for which the Company believes collection is doubtful are recognized in earnings when incurred. As of June 30, 2010 and December 31, 2009, included in Other current assets is approximately \$14.4 million and \$12.9 million, respectively, of escrow receivable balances related to the Blackstone matters described above. These amounts include, among other things, attorneys' fees and costs related to the government investigations manifested by the subpoenas described above, the stock option-related

---

**Table of Contents**

claims described above, and costs related to the qui tam actions described above. As described above, these reimbursement claims are generally being contested by the representative of the former shareholders of Blackstone. To mitigate the risk that some reimbursement claims will not be collected, the Company records a reserve against the escrow receivable during the period in which reimbursement claims are recognized.

Effective October 29, 2007, Blackstone entered into a settlement agreement of a patent infringement lawsuit brought by certain affiliates of Medtronic Sofamor Danek USA Inc. In that lawsuit, the Medtronic plaintiffs had alleged that they were the exclusive licensees of certain U.S. patents and that Blackstone's making, selling, offering for sale, and using its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate, Reliant Cervical Plate, Pillar PEEK and Construx Mini PEEK VBR System products within the U.S. willfully infringed the subject patents. Blackstone denied infringement and asserted that the patents were invalid. The settlement agreement is not expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows. On July 20, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. The Company was subsequently notified by legal counsel of the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

On or about April 10, 2009, the Company received a HIPAA subpoena (HIPAA subpoena) issued by the U.S. Attorney's Office for the District of Massachusetts (the Boston USAO). The subpoena sought documents concerning, among other things, the Company's promotion and marketing of its bone growth stimulator devices. The Boston USAO issued supplemental subpoenas seeking documents in this matter, dated September 21, 2009 and December 16, 2009, respectively. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. Document production in response to the subpoenas is ongoing. The Boston USAO also issued two supplemental subpoenas requiring testimony in this matter dated July 23, 2009 and June 3, 2010. That office excused performance with the July 23, 2009 subpoena indefinitely. On December 21, 2009 and in July 2010, the Boston USAO provided the Company with grand jury subpoenas for the testimony of certain current employees in connection with its ongoing investigation. The Company intends to cooperate with the government's requests. In meetings with the Company and its attorneys regarding this matter, the Boston USAO has informed the Company that it is investigating possible criminal and civil violations of federal law related to the Company's promotion and marketing of its bone growth stimulator devices.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the U.S. District Court for the District of Massachusetts against Orthofix, Inc., the Company, and other companies that have allegedly manufactured bone growth stimulation devices, including Orthologic Corp., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. By order entered on March 24, 2009, the court unsealed the case. The Company and Orthofix, Inc. were served on or about September 8, 2009. With leave of court, Relator's Second Amended Complaint was filed on June 11, 2010. The complaint alleges various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of bone growth stimulation devices. The complaint also includes claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-kickback Act by providing free products to physicians, waiving patients' insurance co-payments, and providing inducements to independent sales agents to generate business. The Company believes that this lawsuit is related to the matter described above involving the HIPAA subpoena. The Company intends to defend vigorously against this lawsuit.

On or about July 2, 2009, the Company obtained a copy of a qui tam complaint filed by Marcus Laughlin that is pending in the U.S. District Court for the District of Massachusetts against the Company. This complaint has been consolidated with the complaint described in the immediately preceding paragraph, and was unsealed on June 30, 2009. The Company was served with the complaint on or about September 9, 2009. With leave of Court, Relator filed a Second Amended Complaint on June 23, 2010. The complaint alleges violations of the federal False Claims Act and various state and local false claims acts, fraudulent billing, illegal kickbacks, conspiracy, and wrongful termination based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products, provided physicians kickbacks in the form of free units, referral fees, and fitting fees. The complaint also alleges that TRICARE has been reimbursing the Company for its Cervical Stim® product without approval to do so. The Company intends to defend vigorously against this lawsuit.

**Table of Contents**

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

On April 22, 2010, the Company obtained a copy of a complaint filed by NuVasive, Inc. ( NuVasive ) and Osiris Therapeutics, Inc. ( Osiris ) in the U.S. District Court for the District of New Jersey against Orthofix International N.V., Orthofix, Inc., Orthofix Holdings, Inc., Orthofix Biologics, Orthofix Spinal Implants, and Musculoskeletal Transplant Foundation. The complaint alleges that the Company's Trinity® Evolution allograft product infringes a U.S. patent owned by Osiris and licensed to NuVasive. The complaint requests the court to enjoin the sale of Trinity® Evolution and award damages to NuVasive and Osiris for the alleged infringement. The Company was served with the complaint on April 28, 2010. On June 8, 2010 the Company filed an answer to the complaint and counterclaim seeking a declaratory judgment that the patent in question is invalid and not infringed. The Company believes that these defenses are meritorious and will continue to defend vigorously against the lawsuit.

During a recent internal management review of Promeca S.A. DE C.V. ( Promeca ), one of its Mexican subsidiaries, the Company received allegations of improper payments, allegedly made by certain of Promeca's local employees in Mexico, to employees of a Mexican governmental health care entity. The Company has engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation focusing on compliance with the Foreign Corrupt Practices Act ( FCPA ) and voluntarily contacted the U.S. Securities and Exchange Commission and the United States Department of Justice to advise both agencies that an internal investigation is underway. During 2009, Promeca accounted for approximately one percent of the Company's consolidated net sales and consolidated total assets. The internal investigation is in its early stages and no conclusions can be drawn at this time as to its outcome; however, the FCPA and related statutes and regulations provide for potential criminal and civil sanctions in connection with FCPA violations, including criminal fines, civil penalties, and disgorgement of past profits.

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

In addition to the foregoing, in the normal course of our business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies. To the extent losses related to these contingencies are both probable and estimable, the Company provides appropriate amounts in the accompanying financial statements.

**Table of Contents**

**Item 1A. Risk Factors**

The following risk factor should be read in conjunction with the other risk factors discussed in Part 1, Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (the Form 10-K). Other than as set forth below, there have been no material changes to our risk factors from the factors discussed in Part I, Item 1A. Risk Factors in our Form 10-K for the fiscal year ended December 31, 2009.

**We are currently investigating allegations of improper payments by local employees of one of our subsidiaries in Mexico and could be exposed to liabilities under the Foreign Corrupt Practices Act. Any determination that the Company or any of its subsidiaries has violated the Foreign Corrupt Practices Act could adversely impact our business and financial position.**

To the extent that we operate outside the United States we are subject to the U.S. Foreign Corrupt Practices Act (FCPA) which prohibits people, or companies subject to United States jurisdiction and their intermediaries, from engaging in bribery or other prohibited payments to foreign officials for the purposes of obtaining or retaining business or gaining an unfair business advantage. It also requires proper record keeping and characterization of such payments in our reports filed with the U.S. Securities and Exchange Commission.

During a recent internal management review of Promeca S.A. DE C.V. (Promeca), one of our Mexican subsidiaries, we received allegations of improper payments, allegedly made by certain of Promeca's local employees in Mexico, to employees of a Mexican governmental health care entity. We have engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation focusing on compliance with the FCPA and voluntarily contacted the U.S. Securities and Exchange Commission and the United States Department of Justice to advise both agencies that an internal investigation is underway. During 2009, Promeca accounted for approximately one percent of the Company's consolidated net sales and consolidated total assets. The internal investigation is in its early stages and no conclusions can be drawn at this time as to its outcome; however, the FCPA and related statutes and regulations do provide for potential monetary penalties as well as criminal and civil sanctions in connection with FCPA violations. If imposed, these monetary penalties and sanctions (which could include fines, criminal penalties and disgorgement of past profits) could be significant, and could adversely impact our business and financial position.

**Table of Contents****ORTHOFIX INTERNATIONAL N.V.****Item 6. Exhibits****a) Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
2.1	Asset Purchase Agreement, dated as of March 8, 2010, by and between Tyco Healthcare Group LP d/b/a Covidien, Covidien AG, Mallinckrodt do Brasil Ltda, Kendall de Mexico S.A. de C.V., Novamedix Limited, Novamedix Distribution Limited, Novamedix Services Limited, Promeca S.A. de C.V., Orthofix do Brasil, Orthofix S.r.l., Orthofix S.A., Intavent Orthofix Limited, Breg Mexico S. de R.I. de CV, and Implantes y Sistemas Medicos, Inc. (filed as an exhibit to the Company's current report on Form 8-K filed March 9, 2010 and incorporated herein by reference).
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
3.2	Articles of Association of the Company as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
10.1*	Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended.
10.2	Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference).
10.3	Orthofix International N.V. Staff Share Option Plan, as amended through April 22, 2003 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007 and incorporated herein by reference).
10.4	Form of Employee Non-Qualified Stock Option Agreement (post-2008 grants) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.5	Form of Non-Employee Director Non-Qualified Stock Option Agreement (post-2008 grants) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.6	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants -- vesting over 3 years) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.7	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants -- 3 year cliff vesting) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.8	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (vesting over 3 years) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).

**Table of Contents**

- 10.9 Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff vesting) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
- 10.10 Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company's current report on Form 8-K filed January 7, 2009, and incorporated herein by reference).
- 10.11 Acquisition Agreement dated as of November 20, 2003, among Orthofix International N.V., Trevor Acquisition, Inc., Breg, Inc. and Bradley R. Mason, as shareholders' representative (filed as an exhibit to the Company's current report on Form 8-K filed January 8, 2004 and incorporated herein by reference).
- 10.12 Amended and Restated Voting and Subscription Agreement dated as of December 22, 2003, among Orthofix International N.V. and the significant shareholders of Breg, Inc. identified on the signature pages thereto (filed as an exhibit to the Company's current report on Form 8-K filed on January 8, 2004 and incorporated herein by reference).
- 10.13 Employment Agreement dated April 15, 2005 between Orthofix Inc. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed April 18, 2005 and incorporated herein by reference).
- 10.14 Amendment to Employment Agreement dated December 29, 2005 between Orthofix Inc. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed December 30, 2005 and incorporated herein by reference).
- 10.15 Form of Indemnity Agreement (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2008 and incorporated herein by reference).
- 10.16 Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
- 10.17 Letter Agreement, dated July 25, 2009, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.18 Letter Agreement, dated January 29, 2010, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.19 Credit Agreement, dated as of September 22, 2006, among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, the several banks and other financial institutions as may from time to time become parties thereunder, and Wachovia Bank, National Association (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).



**Table of Contents**

- 10.20 First Amendment to Credit Agreement, dated September 29, 2008, by and among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, and Wachovia Bank, National Association, as administrative agent on behalf of the Lenders under the Credit Agreement (filed as an exhibit to the Company's current report on Form 8-K filed September 29, 2008 and incorporated herein by reference).
- 10.21 Second Amendment to Credit Agreement, dated February 24, 2010, by and among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, and Wachovia Bank, National Association, as administrative agent on behalf of the Lenders under the Credit Agreement (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2010 and incorporated herein by reference).
- 10.22 Agreement and Plan of Merger, dated as of August 4, 2006, among Orthofix International N.V., Orthofix Holdings, Inc., New Era Medical Limited, Blackstone Medical, Inc. and William G. Lyons, III, as Equityholders' Representative (filed as an exhibit to the Company's current report on Form 8-K filed August 7, 2006 and incorporated herein by reference).
- 10.23 Description of Director Fee Policy (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2010 and incorporated herein by reference).
- 10.24 Summary of Orthofix International N.V. Annual Incentive Program (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2009 and incorporated herein by reference).
- 10.25 Employment Agreement between Orthofix Inc. and Thomas Hein dated as of April 11, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).
- 10.26 Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan, dated April 11, 2008, between Orthofix International N.V. and Thomas Hein (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).
- 10.27 Summary of Consulting Arrangement between Orthofix International N.V. and Peter Hewett (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).
- 10.28 Form of Inducement Grant Nonqualified Stock Option Agreement between Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the current report on Form 8-K of Orthofix International N.V dated September 10, 2008 and incorporated herein by reference).
- 10.29+ Letter Agreement between Orthofix Inc. and Oliver Burckhardt dated August 28, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference).

**Table of Contents**

- 10.30 Notice of Termination from Orthofix Inc. to Oliver Bureckhardt dated August 27, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference).
- 10.31 Second Amended and Restated Performance Accelerated Stock Options Agreement between Orthofix International N.V. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed October 15, 2008 and incorporated herein by reference).
- 10.32 Nonqualified Stock Option Agreement between Orthofix International N.V. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed October 15, 2008 and incorporated herein by reference).
- 10.33 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.34 Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.35 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.36 Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.37 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Bradley R. Mason (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.38 Amendment No. 1 to Amended and Restated Employment Agreement, dated July 31, 2009, by and between Orthofix Inc. and Bradley R. Mason (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.39 Amended and Restated Employment Agreement, entered into on October 23, 2009 and effective as of November 1, 2009, by and between Orthofix Inc. and Bradley R. Mason (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.40 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).

**Table of Contents**

- 10.41 Amendment No. 1 to Amended and Restated Employment Agreement, dated August 4, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
- 10.42 Form of Amendment to Stock Option Agreements (for Alan W. Milinazzo, Robert S. Vaters, Bradley R. Mason, Michael M. Finegan and Michael Simpson) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
- 10.43 Inducement Stock Option Agreement between Orthofix International N.V. and Kevin L. Unger, dated August 17, 2009 (filed as an exhibit to the Company's current report on Form 8-K filed August 17, 2009 and incorporated herein by reference).
- 10.44 Amended and Restated Employment Agreement, entered into on September 4, 2009, by and between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company's current report on Form 8-K filed September 11, 2009 and incorporated herein by reference).
- 10.45 Amended and Restated Employment Agreement, entered into on July 1, 2009, by and between Orthofix Inc. and Eric Brown (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
- 10.46 Amended and Restated Employment Agreement, entered into on November 16, 2009, by and between Breg Inc. and Brad Lee (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
- 10.47+ Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
- 31.1\* Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
- 31.2\* Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
- 32.1\* Section 1350 Certification of Chief Executive Officer.
- 32.2\* Section 1350 Certification of Chief Financial Officer.

\* Filed herewith.

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

**Table of Contents**

**SIGNATURES**

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

ORTHOFIX INTERNATIONAL N.V.

Date: July 29, 2010

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

Date: July 29, 2010

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