

ORTHOFIX INTERNATIONAL N V
Form 10-Q
October 28, 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 September 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

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

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

Indicate by check mark whether the registrant 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 October 26, 2010, 17,726,450 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>	36
Item 4.	<u>Controls and Procedures</u>	37

PART II OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	38
Item 1A.	<u>Risk Factors</u>	42
Item 6.	<u>Exhibits</u>	43
<u>SIGNATURES</u>		48

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)	September 30, 2010 (unaudited)	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,248	\$ 13,328
Restricted cash	21,987	11,630
Trade accounts receivable, less allowance for doubtful accounts of \$7,025 and \$7,205 at September 30, 2010 and December 31, 2009, respectively	132,750	129,777
Inventories, net	85,484	94,624
Deferred income taxes	23,289	20,286
Prepaid expenses	5,366	4,868
Other current assets	29,248	24,981
Total current assets	313,372	299,494
Investments, at cost	345	345
Property, plant and equipment, net	42,362	38,694
Patents and other intangible assets, net	42,794	47,628
Goodwill	176,889	185,175
Deferred taxes and other long-term assets	21,771	19,137
Total assets	\$ 597,533	\$ 590,473
Liabilities and shareholders equity		
Current liabilities:		
Bank borrowings	\$ 2,676	\$ 2,209
Current portion of long-term debt	5,000	3,332
Trade accounts payable	17,739	23,302
Other current liabilities	54,041	59,210
Total current liabilities	79,456	88,053
Long-term debt	217,445	249,132
Deferred income taxes	6,447	6,115
Other long-term liabilities	2,403	6,904
Total liabilities	305,751	350,204
Contingencies (Note 19)		
Shareholders equity:		
Common shares \$0.10 par value; 50,000,000 shares authorized; 17,660,002 and 17,141,710 issued and outstanding as of September 30, 2010 and December 31, 2009, respectively	1,766	1,714
Additional paid-in capital	193,208	177,246
Retained earnings	90,363	54,119

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

Accumulated other comprehensive income	6,445	7,190
Total shareholders' equity	291,782	240,269
Total liabilities and shareholders' equity	\$ 597,533	\$ 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 NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net sales	\$ 138,906	\$ 135,098	\$ 420,573	\$ 401,618
Cost of sales	32,266	31,985	99,046	101,700
Gross profit	106,640	103,113	321,527	299,918
Operating expenses				
Sales and marketing	57,281	55,012	170,756	162,547
General and administrative	21,568	20,819	63,410	64,694
Research and development	7,375	7,863	23,272	25,837
Amortization of intangible assets	1,402	1,668	4,259	4,944
Net gain on sale of vascular operations	20		(12,319)	
	87,646	85,362	249,378	258,022
Operating income	18,994	17,751	72,149	41,896
Other income (expense), net				
Interest expense, net	(3,481)	(6,437)	(14,772)	(18,385)
Loss on refinancing of credit facility	(550)		(550)	
Gain (loss) on interest rate swap		(229)	1,254	1,046
Other expense, net	(674)	(688)	(904)	(586)
	(4,705)	(7,354)	(14,972)	(17,925)
Income before income taxes	14,289	10,397	57,177	23,971
Income tax expense	(5,769)	(4,209)	(20,933)	(8,960)
Net income	\$ 8,520	\$ 6,188	\$ 36,244	\$ 15,011
Net income per common share basic	\$ 0.48	\$ 0.36	\$ 2.06	\$ 0.88
Net income per common share diluted	\$ 0.48	\$ 0.36	\$ 2.03	\$ 0.87
Weighted average number of common shares basic	17,626,319	17,130,247	17,565,414	17,113,891
Weighted average number of common shares diluted	17,836,537	17,215,567	17,824,273	17,174,416

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 NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

(Unaudited, U.S. Dollars, in thousands)	2010	2009
Cash flows from operating activities:		
Net income	\$ 36,244	\$ 15,011
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	15,510	16,064
Amortization of debt costs	215	199
Provision for doubtful accounts	5,901	5,138
Deferred taxes	(2,767)	(2,015)
Share-based compensation	7,124	7,877
Provision for inventory obsolescence	5,872	6,769
Loss on refinancing of credit facility	550	
Change in fair value of interest rate swap	(1,254)	(1,046)
Net gain on sale of vascular operations	(12,319)	
Tax benefit on non-qualified stock options	(1,859)	(2)
Other	507	(131)
Change in operating assets and liabilities:		
Restricted cash	(10,339)	(2,141)
Accounts receivable	(10,080)	(18,357)
Inventories	667	(12,832)
Prepaid expenses and other current assets	(4,810)	(4,415)
Accounts payable	(5,072)	2,314
Current liabilities	(4,678)	15,791
Net cash provided by operating activities	19,412	28,224
Cash flows from investing activities:		
Capital expenditures	(17,160)	(16,073)
Proceeds from sale of investments held at cost		1,711
Net proceeds from sale of assets, principally vascular operations	24,215	
Net cash provided by (used in) investing activities	7,055	(14,362)
Cash flows from financing activities:		
Repayments of long-term debt, net	(29,961)	(22,477)
Proceeds from bank borrowings, net	564	1,581
Net proceeds from issuance of common shares	7,031	7
Payment of refinancing fees	(3,986)	
Cash payment for purchase of minority interest in subsidiary		(1,143)
Tax benefit on non-qualified stock options	1,859	2
Net cash used in financing activities	(24,493)	(22,030)
Effect of exchange rate changes on cash	(54)	374
Net increase (decrease) in cash and cash equivalents	1,920	(7,794)
Cash and cash equivalents at the beginning of the year	13,328	14,594
Cash and cash equivalents at the end of the period	\$ 15,248	\$ 6,800

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

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 nine months ended September 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 nine months ended September 30, 2010 and 2009:

(US\$ in thousands)	Three Months		Nine Months Ended	
	Ended September 30, 2010	2009	September 30, 2010	2009
Cost of sales	\$ 81	\$ 166	\$ 272	\$ 505
Sales and marketing	807	625	2,697	2,290
General and administrative	753	1,632	3,900	4,656
Research and development	35	138	255	426
Total	\$ 1,676	\$ 2,561	\$ 7,124	\$ 7,877

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)	September 30, 2010	December 31, 2009
Raw materials	\$ 11,918	\$ 11,777
Work-in-process	6,837	6,687
Finished products	55,052	59,812
Field inventory	31,752	31,970
Consignment inventory	8,380	8,259
	113,939	118,505
Less reserve for obsolescence	(28,455)	(23,881)
	\$ 85,484	\$ 94,624

NOTE 6: GOODWILL

The changes in the carrying value of goodwill by reportable segment for the period ended September 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 ⁽¹⁾				(7,031)	(7,031)
Foreign currency				(1,255)	(1,255)
At September 30, 2010	\$ 31,793	\$ 9,367	\$ 99,295	\$ 36,434	\$ 176,889

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

NOTE 7: PATENTS AND OTHER INTANGIBLE ASSETS

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

(US\$ in thousands)	September 30, 2010	December 31, 2009
Cost		
Patents and developed technologies	\$ 26,388	\$ 27,961
Trademarks definite lived (subject to amortization)	532	474
Trademarks indefinite lived (not subject to amortization)	23,187	23,187
Distribution networks	44,586	44,586
	94,693	96,208
Accumulated amortization		
Patents and developed technologies	(18,045)	(17,363)
Trademarks definite lived (subject to amortization)	(312)	(243)
Distribution networks	(33,542)	(30,974)
Patents and other intangible assets, net	\$ 42,794	\$ 47,628

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 \$1.6 million for the remainder of 2010 and \$6.2 million, \$5.0 million, \$1.7 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)	September 30, 2010	December 31, 2009
Borrowings under line of credit	\$ 2,676	\$ 2,209

The weighted average interest rates on borrowings under lines of credit as of September 30, 2010 and December 31, 2009 were 4.41% and 5.15%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 5.3 million (\$7.3 million) and 5.8 million (\$8.2 million) at September 30, 2010 and December 31, 2009, respectively, in its Italian line of credit. This line of credit provides the Company the ability 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)	September 30, 2010	December 31, 2009
Long-term obligations	\$ 222,445	\$ 252,400
Other loans		64
	222,445	252,464
Less current portion	(5,000)	(3,332)
	\$ 217,445	\$ 249,132

On August 30, 2010, the Company's wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a Credit Agreement (the New Credit Agreement) with certain domestic direct and indirect subsidiaries of the Company (the Guarantors), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto. In connection with the execution by Orthofix Holdings and the Guarantors of the New Credit Agreement, the previously existing credit agreement, dated as of September 22, 2006 and as subsequently amended on September 29, 2008 and February 24, 2010, among Orthofix Holdings, the Company, and certain subsidiaries, the several banks and other financial institutions parties, and Wachovia Bank, National Association (the Old Credit Agreement), was terminated and all term loan obligations existing were repaid in full using proceeds of the New Credit Agreement.

The New Credit Agreement provides for a five year, \$200.0 million secured revolving credit facility (the Revolving Credit Facility), and a five year, \$100.0 million secured term loan facility (the Term Loan Facility, and together with the Revolving Credit Facility, the Credit Facilities). The full \$100.0 million Term Loan Facility and approximately \$132.4 million of the Revolving Credit Facility were drawn on August 30, 2010. These proceeds were used to repay amounts owed in connection with the termination of the Old Credit Agreement, as well as certain fees

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

related to the establishment of the New Credit Agreement. Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to \$50.0 million upon satisfaction of certain conditions. These increased borrowings may be provided either by one or more existing lenders upon Orthofix Holdings obtaining the agreement of such lenders to increase commitments or by new lenders being added to the Credit Facilities.

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

On September 30, 2010, the Company made a \$10.0 million repayment of its principal balance on the Revolving Credit Facility. As of September 30, 2010, the Company had \$100.0 million outstanding under the Term Loan Facility and \$122.4 million outstanding under the Revolving Credit Facility. In addition, the Company had \$0.2 million of letters of credit outstanding under the Revolving Credit Facility at September 30, 2010. Borrowings under the Credit Facilities bear interest at a floating rate, which is, at Orthofix Holdings' option, either the London Inter-Bank Offered Rate (LIBOR) plus an applicable margin or a base rate (as defined in the New Credit Agreement) plus an applicable margin (in each case subject to adjustment based on financial ratios). Such applicable margin will be up to 3.25% for LIBOR borrowings and up to 2.25% for base rate borrowings depending upon a measurement of the consolidated leverage ratio with respect to the immediately preceding four fiscal quarters. The principal amount of the Term Loan Facility amortizes at the rate of 5%, 15%, 25%, 25% and 30% in year 1, 2, 3, 4 and 5, respectively. Amortization payments are due quarterly beginning with the quarter ending December 31, 2010.

As of September 30, 2010, the entire Term Loan Facility of \$100.0 million is at the LIBOR rate plus a margin of 3.00%. In addition, as of September 30, 2010, \$100.0 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00% and the remaining \$22.4 million of the Revolving Credit Facility is at a base rate (as defined in the New Credit Agreement) plus a margin of 2.00%. The effective interest rate on the Credit Facilities as of September 30, 2010 was 3.5% and the effective interest rate, excluding the amortization of the deferred financing costs, on the Old Credit Agreement as of December 31, 2009 was 8.8%.

Borrowings under the Revolving Credit Facility, which may be made in the future, will be used for working capital, capital expenditures and other general corporate purposes of Orthofix Holdings and its subsidiaries. The Guarantors have guaranteed repayment of Orthofix Holdings obligations under the New Credit Agreement. The obligations of Orthofix Holdings and each of the Guarantors with respect to the Credit Facilities are secured by a pledge of substantially all of the assets of Orthofix Holdings and each of the Guarantors.

The New Credit Agreement requires Orthofix Holdings and the Company to comply with leverage and fixed charge coverage ratios and contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. The New Credit Agreement also includes events of default customary for facilities of this type. Upon the occurrence of an event of default, all outstanding loans may be accelerated and/or the lenders' commitments terminated.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of September 30, 2010 is \$162.9 million compared to \$143.0 million at December 31, 2009. In addition, the New Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities 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 September 30, 2010 is \$22.0 million compared to \$11.6 million at December 31, 2009.

In conjunction with obtaining the Credit Facilities, the Company incurred debt issuance costs of \$4.0 million which are being amortized using the effective interest method over the life of the Credit Facilities. The remaining balance of \$0.6 million in capitalized debt issuance costs related to the Old Credit Agreement that was included in Other Long-term Assets was expensed as a result of the settlement and payoff of this agreement. As of September 30, 2010, \$3.9 million of debt issuance costs, net of accumulated amortization, are included in Other Long-term Assets.

NOTE 10: COMMON SHARES

During the nine month period ended September 30, 2010, there were 518,292 shares of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

Table of Contents**ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****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 gain on cross-currency swap, net of tax of \$437		579	579
Foreign currency translation adjustment ⁽¹⁾	(1,324)		(1,324)
Balance at September 30, 2010	\$ 5,471	\$ 974	\$ 6,445

(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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income	\$ 8,520	\$ 6,188	\$ 36,244	\$ 15,011
Other comprehensive income:				
Unrealized gain (loss) on derivative instrument, net of tax	773	159	579	(2,426)
Foreign currency translation adjustment	3,969	948	(1,324)	6,169
Total comprehensive income	\$ 13,262	\$ 7,295	\$ 35,499	\$ 18,754

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 human cellular and tissue based products (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.

Table of Contents**ORTHOFIX INTERNATIONAL N.V.****NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****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 nine months ended September 30:

For the three month period ended September 30:

(US\$ in thousands)	External Sales		Intersegment Sales	
	2010	2009	2010	2009
Domestic	\$ 57,042	\$ 52,222	\$ 1,438	\$ 1,145
Spinal Implants and Biologics	33,325	28,017	305	291
Breg	22,785	23,724	1,516	1,138
International	25,754	31,135	5,776	7,214
Total	\$ 138,906	\$ 135,098	\$ 9,035	\$ 9,788

For the nine month period ended September 30:

(US\$ in thousands)	External Sales		Intersegment Sales	
	2010	2009	2010	2009
Domestic	\$ 171,377	\$ 155,654	\$ 4,646	\$ 4,853
Spinal Implants and Biologics	95,036	86,562	1,500	1,965
Breg	67,491	70,175	4,163	4,031
International	86,669	89,227	16,548	17,641
Total	\$ 420,573	\$ 401,618	\$ 26,857	\$ 28,490

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

Operating Income (Loss)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(US\$ in thousands)	2010	2009	2010	2009
Domestic	\$ 17,512	\$ 16,505	\$ 55,864	\$ 51,011
Spinal Implants and Biologics	1,873	(2,430) ⁽¹⁾	3,840 ⁽²⁾	(16,898) ⁽³⁾
Breg	3,415	3,210	6,151 ⁽⁴⁾	9,227
International	294	5,066	20,337 ⁽⁵⁾	12,516
Group Activities	(3,906) ⁽⁶⁾	(4,350)	(13,645) ⁽⁶⁾	(14,507)
Eliminations	(194)	(250)	(398)	547

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

Total	\$ 18,994	\$ 17,751	\$ 72,149	\$ 41,896
-------	-----------	-----------	-----------	-----------

- (1) Includes \$0.8 million of research and development expense from collaborative arrangements and \$0.6 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 \$5.7 million of research and development expense from collaborative arrangements and \$3.6 million of restructuring charges.

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

- (4) Includes \$1.7 million of insurance expense to cover product liability claims from its former pain management operations sold in 2008.
- (5) Includes \$12.3 million net gain on the sale of vascular operations (see Note 18).
- (6) Includes \$1.1 million and \$1.8 million, respectively, of professional and legal expense associated with the Company's investigation in Promeca S.A. DE C.V., its Mexican subsidiary, regarding compliance with the Foreign Corrupt Practices Act during the three and nine months ended September 30, 2010 (see Note 19).

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

Sales by Market Sector					
for the three month period ended September 30, 2010					
Spinal					
Implants and					
(US\$ in thousands)	Domestic	Biologics	Breg	International	Total
Spine	\$ 43,236	\$ 33,325	\$	\$ 817	\$ 77,378
Orthopedics	13,806			20,198	34,004
Sports Medicine			22,785	905	23,690
Other				3,834	3,834
Total	\$ 57,042	\$ 33,325	\$ 22,785	\$ 25,754	\$ 138,906

Sales by Market Sector					
for the three month period ended September 30, 2009					
Spinal					
Implants and					
(US\$ in thousands)	Domestic	Biologics	Breg	International	Total
Spine	\$ 39,609	\$ 28,017	\$	\$ 510	\$ 68,136
Orthopedics	12,613			20,637	33,250
Sports Medicine			23,724	940	24,664
Other				9,048	9,048
Total	\$ 52,222	\$ 28,017	\$ 23,724	\$ 31,135	\$ 135,098

Sales by Market Sector					
For the nine month period ended September 30, 2010					
Spinal					
Implants and					
(US\$ in thousands)	Domestic	Biologics	Breg	International	Total
Spine	\$ 130,096	\$ 95,036	\$	\$ 2,579	\$ 227,711
Orthopedics	41,281			65,592	106,873
Sports Medicine			67,491	2,948	70,439
Other				15,550	15,550
Total	\$ 171,377	\$ 95,036	\$ 67,491	\$ 86,669	\$ 420,573

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 nine month period ended September 30, 2009				
	Domestic	Spinal Implants and Biologics	Breg	International	Total
Spine	\$ 117,034	\$ 86,562	\$	\$ 1,399	\$ 204,995
Orthopedics	38,620			56,848	95,468
Sports Medicine			70,175	3,194	73,369
Other				27,786	27,786
Total	\$ 155,654	\$ 86,562	\$ 70,175	\$ 89,227	\$ 401,618

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 completed the restructuring and consolidation during the third quarter of 2010. Total restructuring expenses amounted to \$3.6 million. During the three and nine months ended September 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 was included within Other Current Liabilities in the Company's consolidated balance sheets as of September 30, 2010 and December 31, 2009:

(US\$ in thousands)	Severance
Balance at December 31, 2009	\$ 1,826
Charges	
Cash Payments	(1,826)
Non-cash Items	
Balance at September 30, 2010	\$

NOTE 14: INCOME TAXES

The reported tax provision, as a percentage of income before income taxes, was 36.6% for the nine months ended September 30, 2010. The principal factors affecting the Company's tax rate are the net gain on the sale of the vascular operations (see Note 18) 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 38.9%.

As of September 30, 2010, the Company's gross unrecognized tax benefit was \$0.9 million, inclusive of interest and penalties. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within its global operations in income tax expense. As of September 30, 2010, the Company had approximately \$0.4 million accrued for interest and penalties. The entire \$0.9 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. 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 nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Weighted average common shares basic	17,626,319	17,130,247	17,565,414	17,113,891
Effect of dilutive securities	210,218	85,320	258,859	60,525
Weighted average common shares diluted	17,836,537	17,215,567	17,824,273	17,174,416

For the three and nine months ended September 30, 2010, the Company did not include 1,767,764 and 1,691,289 options, respectively, in the diluted shares outstanding calculation because their exercise price exceeded the average market price of the Company's common stock during the period.

For the three and nine months ended September 30, 2009, the Company did not include 2,953,381 and 3,252,174 options, respectively, in the diluted shares outstanding calculation 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, was scheduled to expire on December 30, 2016. Upon the closing of the Company's new credit facility on August 30, 2010 (see Note 9), Wells Fargo, the financial institution holder of this cross-currency swap, notified the Company of its intent to exit the swap agreement within 45 days (by October 15, 2010). On September 30, 2010, the Company and Wells Fargo terminated this cross-currency swap agreement. Also on September 30, 2010, the Company entered into a new cross-currency swap agreement with JPMorgan Chase Bank and Royal Bank of Scotland PLC (the counterparties) (the replacement swap agreement).

Upon the termination of the cross-currency swap agreement with Wells Fargo on September 30, 2010, the amount representing the current fair value of the terminated cross-currency swap was \$450,000 (the cash settlement amount). As of September 30, 2010, the cash settlement amount was recorded in Other Current Liabilities. The cash settlement amount representing the fair value of the terminated cross-currency swap was paid by the Company to Wells Fargo on October 1, 2010.

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

Under the terms of the replacement swap agreement, the Company pays Euro of 40.7 million at a fixed rate of 5.00% and receives U.S. dollars of \$55.2 million at a fixed rate of 4.635%. The expiration date is December 30, 2016, the date upon which certain intercompany debt, to which the replacement swap agreement applies, matures. The replacement swap agreement is designated as a cash flow hedge. The amount outstanding under the replacement swap agreement and the terminated cross-currency swap agreement as of September 30, 2010 and December 31, 2009 is \$55.2 million and \$53.5 million, respectively. The Company recognized an unrealized gain on the change in fair value of the terminated cross-currency swap arrangement of \$0.8 million and \$0.6 million, net of tax, within other comprehensive income in the three and nine months ended September 30, 2010, respectively. In 2009, the Company recognized an unrealized gain (loss) on the change in fair value of the terminated cross-currency swap arrangement of \$0.2 million and \$(2.4) million, net of tax, within other comprehensive income in the three and nine months ended September 30, 2009, respectively.

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

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.

During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's former 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. For the nine months ended September 30, 2010, the Company recorded a gain of \$1.3 million in the statement of operations. For the three and nine months ended September 30, 2009, the Company recorded a gain (loss) of \$(0.2) and \$1.0 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)	Fair value: favorable (unfavorable)	Balance sheet location	Amount of unrecognized gain (loss) in OCI for the nine months ended September 30, 2010 and 2009
<u>As of September 30, 2010</u>			
Cross-currency swap	\$	Other current liabilities	\$ 579
<u>As of September 30, 2009</u>			
Cross-currency swap	\$ (5,879)	Other long- term liabilities	\$ (2,426)
Interest rate swap	\$ (6,929)	Other current liabilities	\$

(US\$ in thousands)	For the three months ended September 30,		For the nine months ended September 30,	
	2010	2009	2010	2009
Amount of gain (loss) recognized in net income				
Interest rate swap	\$	\$ (229)	\$ 1,254	\$ 1,046

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

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

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

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

As of September 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 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 nature of and short-term maturities of these instruments. The Company's long-term 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 hedge of certain intercompany debt.

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 as of September 30, 2010	Level 1	Level 2	Level 3
Derivative Financial Instruments ⁽¹⁾				
Cash Flow Hedges				
Cross-currency hedge ⁽²⁾	\$	\$	\$	\$

(1) See Note 16, Derivative Instruments.

(2) The Company entered into the replacement cross-currency swap agreement on September 30, 2010 (see Note 16). As such, the replacement cross-currency swap agreement did not have any fair value as of September 30, 2010.

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 would 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 would provide manufacturing and logistics services on behalf of Covidien with respect to certain ImPads for a period of two years and provide other products

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

for a period of 90 days. During the second and third quarters of 2010, the Company completed the transition services agreement and one of the supply agreements (which supplies the other products) with the Covidien Parties. 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 certain litigation costs and the net gain on the sale of the vascular operations as shown in the Condensed Consolidated Statements of Operations for the nine months ended September 30, 2010.

(US\$ in thousands)	Total
Gross cash proceeds received from sale of vascular operations	\$ 27,701
Litigation settlement ⁽¹⁾	3,486
Cash proceeds, net of litigation	24,215
Less:	
Transaction related expenses	1,953
Inventory	1,570
Tangible assets	799
Identifiable intangible assets	543
Goodwill	7,031
Net gain on sale of vascular operations	12,319
Income tax expense	3,498
Gain on sale of vascular operations, net of taxes	\$ 8,821

(1) 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 the Company 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

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

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 August 26, 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 October 31, 2010.

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

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 the Company 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 escrow fund was \$50.0 million. As of September 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.

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Although the Company believes amounts submitted to the escrow fund, net of any reserve, represent valid claims and are realizable, the outcome of each of the escrow claims described above in the preceding paragraphs is difficult to predict. Consequently, any estimate of the amount that may ultimately be returned to the Company from the escrow fund is not certain 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 September 30, 2010 and December 31, 2009, included in Other Current Assets is approximately \$14.6 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 the Company 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. The Boston USAO has 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. (Breg), was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008, when the product line was divested. Since 2008, 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 intends to vigorously defend these cases. On or about August 2, 2010, Breg received a HIPAA subpoena issued by the U.S. Department of Justice, which the Company believes relates to this matter. The subpoena seeks documents from the Company and its subsidiaries for the period January 1, 2000 through the date of the subpoena. Document production in response to the subpoena is ongoing.

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 with certainty 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 nine months ended September 30, 2010 compared to our results of operations for the three and nine months ended September 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 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 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.

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 Ascend[®] 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 re-organization 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.

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

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

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

Table of Contents

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 nine months ended September 30, 2010 and all of 2009, we have used a derivative instrument 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 the operations of our subsidiary Orthofix Inc. within the U.S. 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 September 30,		2009	Growth
		Percent of Total Net Sales	Net Sales		
Domestic	\$ 57,042	41%	\$ 52,222	39%	9%
Spinal Implants and Biologics	33,325	24%	28,017	21%	19%
Breg	22,785	16%	23,724	17%	-4%
International	25,754	19%	31,135	23%	-17%
Total	\$ 138,906	100%	\$ 135,098	100%	3%

(US\$ in thousands)	2010	Nine Months Ended September 30,		2009	Growth
		Percent of Total Net Sales	Net Sales		
Domestic	\$ 171,377	41%	\$ 155,654	39%	10%
Spinal Implants and Biologics	95,036	23%	86,562	22%	10%
Breg	67,491	16%	70,175	17%	-4%
International	86,669	20%	89,227	22%	-3%
Total	\$ 420,573	100%	\$ 401,618	100%	5%

Table of Contents*Market Sector:*

(US\$ in thousands)	2010		Three Months Ended September 30, 2009		Reported Growth	Constant Currency Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales		
Spine	\$ 77,378	56%	\$ 68,136	50%	14%	14%
Orthopedics	34,004	24%	33,250	25%	2%	6%
Sports Medicine	23,690	17%	24,664	18%	-4%	-4%
Other	3,834	3%	9,048	7%	-58%	-56%
Total	\$ 138,906	100%	\$ 135,098	100%	3%	4%

(US\$ in thousands)	2010		Nine Months Ended September 30, 2009		Reported Growth	Constant Currency Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales		
Spine	\$ 227,711	54%	\$ 204,995	51%	11%	11%
Orthopedics	106,873	25%	95,468	24%	12%	11%
Sports Medicine	70,439	17%	73,369	18%	-4%	-4%
Other	15,550	4%	27,786	7%	-44%	-45%
Total	\$ 420,573	100%	\$ 401,618	100%	5%	4%

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 September 30, 2010		Three Months Ended September 30, 2009		Nine Months Ended September 30, 2010		Nine Months Ended September 30, 2009	
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Net sales	100	100	100	100	100	100	100	100
Cost of sales	23	24	24	24	24	24	25	25
Gross profit	77	76	76	76	76	76	75	75
Operating expenses								
Sales and marketing	41	41	41	41	41	41	41	41
General and administrative	16	15	15	15	15	15	16	16
Research and development	5	6	6	6	6	6	7	7
Amortization of intangible assets	1	1	1	1	1	1	1	1
Net gain on sale of vascular operations						(3)		
Total operating income	14	13	13	13	17	17	10	10
Net income	6	5	5	5	9	9	4	4

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

Net sales increased 3% to \$138.9 million in the third quarter of 2010 compared to \$135.1 million for the same period last year. The impact of foreign currency decreased sales by \$1.5 million during the third quarter of 2010 when compared to the third quarter of 2009.

*Sales by Business Segment:***Domestic**

Net sales in Domestic increased to \$57.0 million in the third quarter of 2010 compared to \$52.2 million for the same period last year, an increase of 9%. Domestic's net sales represented 41% and 39% of total net sales during the third quarter of 2010 and 2009, respectively. The increase in Domestic's net sales was the result of a 9% increase in sales in our Spine market sector, which in turn was mainly driven by increased sales of our Spinal-Stim[®] and Cervical-Stim[®] products of 8% 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 9% increase in our Orthopedics market sector which included a significant increase in our HCT/P products, primarily Trinity[®] Evolution. These sales increases in the Orthopedics market sector were partially offset by a decrease in the sales of our internal and external fixation devices.

Domestic Sales by Market Sector:

(US\$ in thousands)	Net Sales for the		
	Three Months Ended September 30,		
	2010	2009	Growth
Spine	\$ 43,236	\$ 39,609	9%
Orthopedics	13,806	12,613	9%
Total	\$ 57,042	\$ 52,222	9%

Spinal Implants and Biologics

Net sales in Spinal Implants and Biologics increased \$5.3 million to \$33.3 million in the third quarter of 2010 compared to \$28.0 million for the same period last year, an increase of 19%. Spinal Implants and Biologics' net sales represented 24% and 21% of our total net sales during the third quarter of 2010 and 2009, respectively. The increased sales related to a 23% increase in our thoracolumbar products, primarily from a sales increase in the Firebird pedicle screw system, which had a full market release during the second quarter of 2009. Sales of our biologics products increased, mainly due to the continued strong sales of Trinity[®] Evolution over the same period in the prior year. Full market release of our Trinity[®] Evolution stem cell-based allograft occurred on July 1, 2009. In addition, sales of our cervical products increased by 11%, when compared to the same period in the prior year, as a result of the increased sales in our 3° and Ascent[®] LE product lines. All of Spinal Implants and Biologics' sales are recorded in our Spine market sector.

Breg

Net sales in Breg decreased \$0.9 million to \$22.8 million in the third quarter of 2010 compared to \$23.7 million for the same period last year, a decrease of 4%. Breg's net sales represented 16% and 17% of our total net sales during the third 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 gross revenues. Excluding the impact of this change, net sales in Breg for the third quarter 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 3% reduction in sales of our Breg bracing products and a 5% 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.

Table of Contents**International**

Net sales in International decreased 17% to \$25.8 million in the third quarter of 2010 compared to \$31.1 million for the same period last year. International's net sales represented 19% and 23% of our total net sales in the third 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 include the Laryngeal Mask product and other vascular products. Other distributed products decreased to \$3.8 million in the third quarter of 2010 compared to \$9.0 million in the same period for the prior year. During the first quarter of 2010, we disposed of our vascular operations. (See Net Gain on Sale of Vascular Operations further below). In June 2010 and in October 2009, we transitioned out of our agreements to distribute the Laryngeal Mask product in the United Kingdom and Italy, respectively. In addition to these sales decreases of our Other distributed products, sales of our Orthopedics sector decreased 2% to \$20.2 million in the third quarter of 2010 compared to \$20.6 million in the same period of the prior year. The impact of foreign currency decreased our International net sales by 5%, or \$1.4 million, during the third quarter of 2010 as compared to the third quarter of 2009, principally due to the weakening of the Euro against the U.S. dollar, offset by the strengthening of certain currencies outside of Europe. On a constant currency basis, sales for the Orthopedics sector increased 4% in the third quarter of 2010 when compared to the prior year. Within the Orthopedics sector, constant currency sales of our internal and external fixation devices, Physio-Stim® and deformity correction products increased when compared with the same period last year.

International Sales by Market Sector:

(US\$ in thousands)	Net Sales for the		Reported Growth	Constant Currency Growth
	Three Months Ended September 30, 2010	Three Months Ended September 30, 2009		
Spine	\$ 817	\$ 510	60%	60%
Orthopedics	20,198	20,637	-2%	4%
Sports Medicine	905	940	-4%	4%
Other	3,834	9,048	-58%	-57%
Total	\$ 25,754	\$ 31,135	-17%	-13%

Sales by Market Sector:

Sales of our Spine products increased to \$77.4 million in the third quarter of 2010 compared to \$68.1 million in the third quarter of 2009. Sales of our Cervical-Stim® and Spinal-Stim® products increased 10% and 8%, respectively, in the third quarter of 2010 compared to 2009. In addition, sales of our Spinal Implants and Biologics products increased 20% over the same period in the prior year due to increases in our thoracolumbar, cervical and biologics products, previously discussed. Spine product sales were 56% and 50% of our total net sales in the third quarter of 2010 and 2009, respectively.

Sales of our Orthopedics products increased 2%, and 6% on a constant currency basis, to \$34.0 million in the third quarter of 2010 compared to \$33.3 million for the same period last year due to increased sales of our internal and external fixation devices and HCT/P products. Orthopedic product sales were 24% and 25% of our total net sales in the third quarter of 2010 and 2009, respectively.

Sales of our Sports Medicine products decreased 4% to \$23.7 million in the third quarter of 2010 compared to \$24.7 million for the same period last year. As discussed above, net sales would have decreased by 2% when comparing the third 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 3% reduction in sales of our bracing products and a 5% decrease in our cold therapy 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 third quarter of 2010 and 2009, respectively.

Table of Contents

Sales of our Other products which include our non-core distributed product lines and our former Vascular and Laryngeal Mask product lines decreased 58% to \$3.8 million in the third quarter of 2010 compared to \$9.0 million for the same period last year. During the first quarter of 2010, we disposed of our vascular operations. (See Net Gain on Sale of Vascular Operations further below). In June 2010 and in October 2009, we transitioned out of our agreements to distribute the Laryngeal Mask product in the United Kingdom and Italy, respectively. Other product sales were 3% and 7% of our total net sales in the third quarter of 2010 and 2009, respectively.

Gross Profit Our gross profit increased 3% to \$106.6 million in the third quarter of 2010, compared to \$103.1 million for the same period last year. Gross profit, as a percent of net sales, in the third quarter of 2010 was 76.8% compared to 76.3% for the same period last year. The increase in the gross profit is primarily due to the increased sales of our higher margin stimulation products and Spinal Implants and Biologics products.

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 \$2.3 million, or 4%, to \$57.3 million in the third quarter of 2010 compared to \$55.0 million in the third quarter of 2009. As a percent of net sales, sales and marketing expense was 41.2% and 40.7% in the third quarter of 2010 and 2009, respectively. The increase was due primarily to our exit from the non-core vascular and anesthesia businesses, which carried lower sales and marketing expenses, as a percentage of net sales.

General and Administrative Expense General and administrative expense increased \$0.8 million, or 4%, in the third quarter of 2010 to \$21.6 million compared to \$20.8 million in the third quarter of 2009. This included the impact of approximately \$3.7 million in legal expenses associated with an investigation of the bone growth stimulation industry, as well as costs incurred in connection with our internal investigation into the compliance with the Foreign Corrupt Practices Act with our subsidiary in Mexico. General and administrative expenses in the third quarter of 2009 included \$0.6 million in costs associated with the reorganization and consolidation plan at our Spinal Implants and Biologics division. General and administrative expense, as a percent of net sales, was 15.5% in the third 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 third quarter of 2010 to \$7.4 million compared to \$7.9 million for the same period last year. During the third quarter of 2009, as a result of our collaborative arrangement with Intelligent Implant Systems (IIS), we made a \$0.8 million milestone payment. As a percent of net sales, research and development expense was 5.3% in the third quarter of 2010 compared to 5.8% for the same period last year.

Amortization of Intangible Assets Amortization of intangible assets decreased \$0.3 million in the third quarter of 2010 to \$1.4 million compared to \$1.7 million for the same period last year.

Net Gain on Sale of Vascular Operations As previously announced in the first quarter of 2010, we 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 third quarter of 2010, we recorded additional transaction related expenses of approximately \$20,000 due to a revision in its estimated costs that were previously disclosed.

Interest Expense, net Interest expense, net was \$3.5 million for the third quarter of 2010 compared to \$6.4 million for the same period last year. The decrease was primarily the result of a lower year-over-year outstanding debt balance, a lower interest rate resulting from the payoff of the interest rate swap in June 2010 and our refinancing of the outstanding long-term debt facility in August 2010.

Loss on Refinancing of Credit Facility In the third quarter of 2010, we incurred \$0.6 million of expense related to the write-off of the remaining capitalized debt placement costs associated with the former credit facility agreement.

Table of Contents

Gain on Interest Rate Swap In June 2008, we entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's former 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, we settled the Swap with the financial institution holder of the derivative instrument. For the three months ended September 30, 2009, we recorded a non-cash loss of \$(0.2) related to the change in the fair value of the Swap.

Other Expense, net Other expense, net reflected an expense of \$(0.7) million for both the third quarters of 2010 and 2009. 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 40.4% and 40.5% during the third quarters of 2010 and 2009, respectively. The effective tax rate for the third 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 we do not currently recognize a tax benefit. We do not believe that it is more likely than not that we 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 third quarter of 2010 was \$8.5 million, or \$0.48 per basic and diluted share compared to a net income of \$6.2 million, or \$0.36 per basic share and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,626,319 and 17,130,247 during the third quarters of 2010 and 2009, respectively. The weighted average number of diluted common shares outstanding was 17,836,537 and 17,215,567 during the third quarters of 2010 and 2009, respectively.

Nine Months Ended September 30, 2010 Compared to Nine Months Ended September 30, 2009

Net sales increased 5% to \$420.6 million during the first nine months of 2010 compared to \$401.6 million for the same period last year. The impact of foreign currency increased sales by \$1.5 million during the first nine months of 2010 when compared to the same period last year.

Sales by Business Segment:**Domestic**

Net sales in Domestic increased to \$171.4 million for the nine months ended September 30, 2010 compared to \$155.7 million for the same period last year, an increase of 10%. Domestic's net sales represented 41% and 39% of our total net sales for the nine months ended September 30, 2010 and 2009, respectively. The increase in Domestic's net sales was primarily the result of an 11% increase in sales in our Spine market sector, mainly driven by increased sales of our Spinal-Stim® and Cervical-Stim® products of 11% each when compared to the same period in the prior year. The increase in Domestic's net sales was also attributable to a 7% increase in our Orthopedics market sector which included sales increases in both of our external fixation and deformity correction product lines, as well as an increase in our HCT/P products, primarily Trinity® Evolution.

Domestic Sales by Market Sector:

(US\$ in thousands)	Net Sales for the		
	Nine Months Ended September 30,		Growth
	2010	2009	
Spine	\$ 130,096	\$ 117,034	11%
Orthopedics	41,281	38,620	7%
Total	\$ 171,377	\$ 155,654	10%

Table of Contents***Spinal Implants and Biologics***

Net sales in Spinal Implants and Biologics increased \$8.5 million to \$95.0 million for the nine months ended September 30, 2010 compared to \$86.6 million for the same period last year, an increase of 10%. Spinal Implants and Biologics net sales represented 23% and 22% of our total net sales during the nine months ended September 30, 2010 and 2009, respectively. The increase in sales was primarily related to an 18% increase in our thoracolumbar products due primarily from an increase in the sales of our Firebird pedicle screw system, which had a full market release during the second quarter of 2009. Sales of our interbody products increased when compared to the same period in the prior year, as a result of our introduction of the Pillar SA interbody device during the third quarter of 2009. These increases were partially offset by a 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 which was previously recorded as full end user sales for our 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.

Breg

Net sales in Breg decreased \$2.7 million to \$67.5 million during the nine months ended September 30, 2010 compared to \$70.2 million for the same period last year, a decrease of 4%. Breg's net sales represented 16% and 17% of our total net sales for the nine months ended September 30, 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 gross revenues. Excluding the impact of this change, net sales in Breg for the nine months ended September 30, 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. Sales of our cold therapy products decreased 1% 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.

International

Net sales in International decreased 3% to \$86.7 million for the nine months ended September 30, 2010 compared to \$89.2 million for the same period last year. International's net sales represented 20% and 22% of our total net sales for the nine months ended September 30, 2010 and 2009, respectively. The impact of foreign currency increased International net sales by 2%, or \$1.5 million, during the nine months ended September 30, 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 our Orthopedics sector increased 13% for the nine months ended September 30, 2010 when compared to the prior year. Within the Orthopedics sector, constant currency sales of our internal and external devices and our deformity correction products increased when compared with the same period last year. Partially offsetting these sales increases was a reduction of sales in our Other distributed products which include the Laryngeal Mask product and vascular products. Other distributed products decreased to \$15.6 million for the nine months ended September 30, 2010 compared to \$27.8 million for the same period last year. During the first quarter of 2010, we disposed of our vascular operations. (See Net Gain on Sale of Vascular Operations further below). In June 2010 and October 2009, we transitioned out of our agreements to distribute the Laryngeal Mask product in the United Kingdom and Italy, respectively.

Table of Contents*International Sales by Market Sector:*

(US\$ in thousands)	Net Sales for the		Reported Growth	Constant Currency Growth
	Nine Months Ended September 30, 2010	2009		
Spine	\$ 2,579	\$ 1,399	84%	84%
Orthopedics	65,592	56,848	15%	13%
Sports Medicine	2,948	3,194	-8%	-8%
Other	15,550	27,786	-44%	-45%
Total	\$ 86,669	\$ 89,227	-3%	-5%

Sales by Market Sector:

Sales of our Spine products increased to \$227.7 million for the nine months ended September 30, 2010 compared to \$205.0 million for the same period last year. Sales of our Cervical-Stim[®] and Spinal-Stim[®] products increased 11% each for the nine months ended September 30, 2010 compared to the same period last year. In addition, sales of our Spinal Implants and Biologics products increased 11% over the same period in the prior year due to increased sales of our thoracolumbar and interbody products. Spine product sales were 54% and 51% of our total net sales for the nine months ended September 30, 2010 and 2009, respectively.

Sales of our Orthopedics products increased \$11.4 million, or 12%, to \$106.9 million for the nine months ended September 30, 2010 compared to \$95.5 million for the same period last year due to increased sales of our internal and external fixation devices, deformity correction products and HCT/P products. Orthopedic product sales were 25% and 24% of our total net sales for the nine months ended September 30, 2010 and 2009, respectively.

Sales of our Sports Medicine products decreased 4% to \$70.4 million for the nine months ended September 30, 2010 compared to \$73.4 million for the same period last year. As discussed above, net sales would have decreased by 2% when comparing the nine months ended September 30, 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 for the nine months ended September 30, 2010 and 2009, respectively.

Sales of our Other products, which include our non-core distributed product lines and our former Vascular and Laryngeal Mask product lines decreased 44% to \$15.6 million for the nine months ended September 30, 2010 compared to \$27.8 million for the same period last year. During the first quarter of 2010, we disposed of our vascular operations. (See Net Gain on Sale of Vascular Operations further below). In June 2010 and October 2009, we transitioned out of our agreements to distribute the Laryngeal Mask product in the United Kingdom and Italy, respectively. Other product sales were 4% and 7% of our total net sales for the nine months ended September 30, 2010 and 2009, respectively.

Gross Profit Our gross profit increased 7% to \$321.5 million for the nine months ended September 30, 2010, compared to \$299.9 million for the same period last year. Gross profit, as a percent of net sales, for the nine months ended September 30, 2010 was 76.4% compared to 74.7% for the same period last year. The gross profit for the nine months ended September 30, 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 during nine months ended September 30, 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 our distribution agreement on June 30, 2009. The increase in the gross profit is primarily due to the increased sales of our higher margin stimulation products and Spinal Implants and Biologics products. 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.

Table of Contents

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 \$8.2 million, or 5%, to \$170.8 million for the nine months ended September 30, 2010 compared to \$162.5 million for the same period last year. As a percent of net sales, sales and marketing expense was 40.6% and 40.5% for the nine months ended September 30, 2010 and 2009, respectively.

General and Administrative Expense General and administrative expense decreased \$1.3 million, or 2%, for the nine months ended September 30, 2010 to \$63.4 million compared to \$64.7 million for the same period last year. The decrease is primarily due to a restructuring charge recorded in the first nine months 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 our spine stimulation and U.S. orthopedics business in the Dallas, TX area. In addition, during the first quarter of 2009, we incurred \$0.7 million of costs incurred in connection with a proxy contest. General and administrative expense, as a percent of net sales, was 15.1% for the nine months of 2010 compared to 16.1% for the same period last year.

Research and Development Expense Research and development expense decreased \$2.6 million for the nine months ended September 30, 2010 to \$23.3 million compared to \$25.8 million for the same period last year. During the nine months ended September 30, 2010, we incurred \$3.2 million in expenses related to research and development projects associated with our orthopedics and long bone stimulation devices. During the same period in 2009, we incurred \$3.9 million and \$1.8 million in expenses primarily related to collaborative arrangements with the Musculoskeletal Transplant Foundation (MTF) and IIS, respectively. As a percent of net sales, research and development expense was 5.5% during the nine months ended September 30, of 2010 compared to 6.4% for the same period last year.

Amortization of Intangible Assets Amortization of intangible assets decreased \$0.7 million for the nine months ended September 30, 2010 to \$4.3 million compared to \$4.9 million for the same period last year.

Net Gain on Sale of Vascular Operations The net gain on sale of vascular operations was \$12.3 million for the nine months ended September 30, 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 nine months of 2009.

Interest Expense, net Interest expense, net was \$14.8 million for the nine months ended September 30, 2010 compared to \$18.4 million for the same period last year. The decrease was primarily the result of a lower year-over-year outstanding debt balance, a lower interest rate resulting from the payoff of the interest rate swap in June 2010 and the refinancing of our outstanding long-term debt facility in August 2010.

Loss on Refinancing of Credit Facility For the nine months ended September 30, 2010, we incurred \$0.6 million of expense related to the write-off of the remaining capitalized debt placement costs associated with the former credit facility agreement.

Gain on Interest Rate Swap In June 2008, we entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's former 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, we settled the Swap with the financial institution holder of the derivative instrument. We recorded a gain of \$1.3 million and \$1.0 million during the nine months ended September 30, 2010 and 2009, respectively, related to the change in the fair value of the Swap.

Table of Contents

Other Expense, net Other expense, net reflected an expense of \$(0.9) million during the nine months ended September 30, 2010 compared to \$(0.6) 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 36.6% and 37.4% for the nine months ended September 30, 2010 and 2009, respectively. The effective tax rate for the first nine months of 2010 was affected by the net gain on the sale of vascular operations and the mix of earnings among various tax jurisdictions. Without the sale of the vascular operations, our tax rate would have been approximately 38.9%. We also incur losses in a number of foreign jurisdictions for which we do not currently recognize a tax benefit. We do not believe that it is more likely than not that we 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 nine months ended September 30, 2010 was \$36.2 million, or \$2.06 per basic share and \$2.03 per diluted share, compared to net income of \$15.0 million, or \$0.88 per basic share and \$0.87 per diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,565,414 and 17,113,891 during the nine months ended September 30, 2010 and 2009, respectively. The weighted average number of diluted common shares outstanding was 17,824,273 and 17,174,416 during the nine months ended September 30, 2010 and 2009, respectively.

Liquidity and Capital Resources

Cash and cash equivalents at September 30, 2010 were \$37.2 million, of which \$22.0 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 \$19.4 million for the nine months ended September 30, 2010 compared to net cash provided by operating activities of \$28.2 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 the net gain on sale of vascular operations) and changes in working capital, including changes in restricted cash. The decrease in net cash provided by operating activities was due to the increased consumption of working capital, partially offset by the increase in net income. Working capital accounts consumed \$34.3 million of cash in the nine months ended September 30, 2010 compared to \$19.6 million for the same period last year. The higher consumption of working capital in the 2010 period can be attributed to changes in other current liabilities of \$20.5 million, which includes the effect on cash of \$4.8 million to settle our interest rate swap, restricted cash of \$8.2 million and accounts payable of \$7.4 million, which was partially offset by improvements in the change in inventory of \$13.5 million and trade accounts receivable of \$8.3 million. When excluding the net gain on sale of vascular operations (which is a non-cash item), net income increased \$8.9 million in the nine months ended September 30, 2010 versus the comparable period in the prior year. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 88 days at September 30, 2010 compared to 87 days at September 30, 2009 and inventory turns of 1.5 times and 1.3 times for September 30, 2010 and September 30, 2009, respectively.

Net cash provided by investing activities was \$7.1 million during the nine months ended September 30, 2010 compared to net cash used in investing activities of \$14.4 million during the same period last year. During the first quarter of 2010, we sold our vascular operations with cash proceeds of \$24.2 million, net of litigation settlement costs. During the nine months ended September 30, 2010 and 2009, we invested \$17.2 million and \$16.1 million in capital expenditures, respectively. During the nine months ended September 30, 2009, we sold our remaining ownership in OPED AG, a German bracing company, for net proceeds of \$1.7 million.

Table of Contents

Net cash used in financing activities was \$24.5 million for the nine months ended September 30, 2010 compared to \$22.0 million for the same period last year. During the nine months ended September 30, 2010, we repaid approximately \$30.0 million against the principal on our senior secured term loan compared to \$22.5 million during the nine months ended September 30, 2009. During the nine months ended September 30, 2010, we paid \$4.0 million of debt issuance costs in conjunction with the our new credit facility entered into on August 30, 2010. During the nine months ended September 30, 2010, we received proceeds of \$7.0 million from the issuance of 518,292 shares of our common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

On August 30, 2010, the Company's wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a Credit Agreement (the New Credit Agreement) with certain domestic direct and indirect subsidiaries of the Company (the Guarantors), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto. In connection with the execution by Orthofix Holdings and the Guarantors of the New Credit Agreement, the previously existing credit agreement, dated as of September 22, 2006 and as subsequently amended on September 29, 2008 and February 24, 2010, among Orthofix Holdings, the Company, and certain subsidiaries, the several banks and other financial institutions parties, and Wachovia Bank, National Association (the Old Credit Agreement), was terminated and all term loan obligations existing were repaid in full using proceeds of the New Credit Agreement.

The New Credit Agreement provides for a five year, \$200.0 million secured revolving credit facility (the Revolving Credit Facility), and a five year, \$100.0 million secured term loan facility (the Term Loan Facility, and together with the Revolving Credit Facility, the Credit Facilities). The full \$100.0 million Term Loan Facility and approximately \$132.4 million of the Revolving Credit Facility were drawn on August 30, 2010. These proceeds were used to repay amounts owed in connection with the termination of the Old Credit Agreement, as well as certain fees related to the establishment of the New Credit Agreement. Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to \$50.0 million upon satisfaction of certain conditions. These increased borrowings may be provided either by one or more existing lenders upon Orthofix Holdings obtaining the agreement of such lenders to increase commitments or by new lenders being added to the Credit Facilities.

On September 30, 2010, we made a \$10.0 million repayment of its principal balance on the Revolving Credit Facility. As of September 30, 2010, we had \$100.0 million outstanding under the Term Loan Facility and \$122.4 million outstanding under the Revolving Credit Facility. In addition, we had \$0.2 million of letters of credit outstanding under the Revolving Credit Facility at September 30, 2010. Borrowings under the Credit Facilities bear interest at a floating rate, which is, at Orthofix Holdings' option, either the London Inter-Bank Offered Rate (LIBOR) plus an applicable margin or a base rate (as defined in the New Credit Agreement) plus an applicable margin (in each case subject to adjustment based on financial ratios). Such applicable margin will be up to 3.25% for LIBOR borrowings and up to 2.25% for base rate borrowings depending upon a measurement of the consolidated leverage ratio with respect to the immediately preceding four fiscal quarters. The principal amount of the Term Loan Facility amortizes at the rate of 5%, 15%, 25%, 25% and 30% in year 1, 2, 3, 4 and 5, respectively. Amortization payments are due quarterly beginning with the quarter ending December 31, 2010.

As of September 30, 2010, the entire Term Loan Facility of \$100.0 million is at the LIBOR rate plus a margin of 3.00%. In addition, as of September 30, 2010, \$100.0 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00% and the remaining \$22.4 million of the Revolving Credit Facility is at a base rate (as defined in the New Credit Agreement) plus a margin of 2.00%. The effective interest rate on the Credit Facilities as of September 30, 2010 was 3.5% and the effective interest rate, excluding the amortization of the deferred financing costs, on the Old Credit Agreement as of December 31, 2009 was 8.8%.

Borrowings under the Revolving Credit Facility, which may be made in the future, will be used for working capital, capital expenditures and other general corporate purposes of Orthofix Holdings and its subsidiaries. The Guarantors have guaranteed repayment of Orthofix Holdings obligations under the New Credit Agreement. The obligations of Orthofix Holdings and each of the Guarantors with respect to the Credit Facilities are secured by a pledge of substantially all of the assets of Orthofix Holdings and each of the Guarantors.

The New Credit Agreement requires Orthofix Holdings and the Company to comply with leverage and fixed charge coverage ratios on a consolidated basis. We were in compliance with these financial covenants as measured at September 30, 2010. As defined in the New Credit Agreement, our leverage ratio cannot exceed 3.25 and our fixed charge ratio must be greater than or equal to 1.25. At September 30, 2010, our leverage and fixed charge ratios were 2.0 and 2.9, respectively. The New Credit Agreement contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. The New Credit Agreement also includes events of default customary for facilities of this type. A breach of any of these covenants could result in an event of default under the New Credit Agreement, which could permit acceleration of the debt payments under the facility.

Table of Contents

As defined in the New Credit Agreement, the leverage ratio we cannot exceed is 3.25 for the life of the agreement and the fixed charge coverage ratio must be greater or equal to 1.25 for the life of the agreement. Based on our projected earnings, we believe that we 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.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of September 30, 2010 is \$162.9 million compared to \$143.0 million at December 31, 2009. In addition, the New Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities 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 September 30, 2010 is \$22.0 million compared to \$11.6 million at December 31, 2009.

In conjunction with obtaining the Credit Facilities, we incurred debt issuance costs of \$4.0 million which are being amortized using the effective interest method over the life of the Credit Facilities. The remaining balance of \$0.6 million in capitalized debt issuance costs related to the Old Credit Agreement that was included in Other Long-term Assets was expensed as a result of the settlement and payoff of this agreement. As of September 30, 2010, \$3.9 million of debt issuance costs, net of accumulated amortization, are included in Other Long-term Assets.

At September 30, 2010, we had outstanding borrowings of \$2.7 million and unused available lines of credit of approximately 5.3 million (\$7.3 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the ability 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 \$77.6 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 projects, formerly mentioned, over the near term.

In the fourth quarter of 2008, as part of our strategic plan to strengthen the business, we 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 our spine stimulation and U.S. orthopedics business in the Dallas, TX area. We completed the restructuring and consolidation during the third quarter of 2010. Total restructuring expenses amounted to \$3.6 million. During the three and nine months ended September 30, 2010, we did not record any restructuring charges.

Table of Contents

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

(US\$ in thousands)	Severance
Balance at December 31, 2009	\$ 1,826
Charges	
Cash Payments	(1,826)
Non-cash Items	
Balance at September 30, 2010	\$

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 would 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 would 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 and third quarters of 2010, the Company completed the transition services agreement and one of the supply agreements (which supplies the other products) with the Covidien Parties. 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 certain litigation costs and the net gain on the sale of the vascular operations as shown in the Condensed Consolidated Statements of Operations for the nine months ended September 30, 2010.

(US\$ in thousands)	Total
Gross cash proceeds received from sale of vascular operations	\$ 27,701
Litigation settlement ⁽¹⁾	3,486
Cash proceeds, net of litigation	24,215
Less:	
Transaction related expenses	1,953
Inventory	1,570
Tangible assets	799
Identifiable intangible assets	543
Goodwill	7,031
Net gain on sale of vascular operations	12,319
Income tax expense	3,498

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

Gain on sale of vascular operations, net of taxes

\$ 8,821

- (1) 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 September 30, 2010, we had a cross-currency swap in place to minimize foreign currency exchange risk related to a 40.7 million intercompany note.

We are exposed to interest rate risk in connection with our Term Loan Facility and Revolving Credit Facility, which bear interest at floating rates based on LIBOR plus an applicable borrowing margin or at a base rate (as defined in the New Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant.

As of September 30, 2010, the entire Term Loan Facility of \$100.0 million is at the LIBOR rate plus a margin of 3.00%. As of September 30, 2010, \$100.0 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00% and the remaining \$22.4 million of the Revolving Credit Facility is at a base rate (as defined in the New Credit Agreement) plus a margin of 2.00%. These margins are adjusted based upon the measurement of the consolidated leverage ratio of the Company and its subsidiaries with respect to the immediately preceding four fiscal quarters. As of September 30, 2010, our effective interest rate on our Credit Facilities was 3.5%. Based on the balance outstanding under the Credit Facilities as of September 30, 2010, an immediate change of one percentage point in the applicable interest rate on the Term Loan Facility and Revolving Credit Facility would cause a change in interest expense of approximately \$0.6 million on a quarterly basis and \$2.2 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 September 30, 2010, we had an un-hedged long-term intercompany balance denominated in Euro of approximately 22.7 million (\$30.9 million). We recorded a foreign currency loss of \$1.4 million related to this un-hedged long-term intercompany balance in accumulated other comprehensive income during the nine months ended September 30, 2010, which resulted from the weakening of the Euro against the U.S. dollar during the period. For the nine months ended September 30, 2010, we recorded a foreign currency loss of \$0.7 million on the statement of operations resulting from gains and losses in foreign currency transactions.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the nine months ended September 30, 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 nine months ended September 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 September 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 the Company 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 August 26, 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 October 31, 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 the Company 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 September 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.

Although the Company believes amounts submitted to the escrow fund, net of any reserve, represent valid claims and are realizable, the outcome of each of the escrow claims described above in the preceding paragraphs is difficult to predict. Consequently, any estimate of the amount that may ultimately be returned to the Company from the escrow fund is not certain 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 September 30, 2010 and December 31, 2009, included in Other Current Assets is approximately \$14.6 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.

Table of Contents

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 the Company 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. The Boston USAO has 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 (Breg), was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008, when the product line was divested. Since 2008, 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 intends to vigorously defend these cases. On or about August 2, 2010, Breg received a HIPAA subpoena issued by the U.S. Department of Justice, which the Company believes relates to this matter. The subpoena seeks documents from the Company and its subsidiaries for the period January 1, 2000 through the date of the subpoena. Document production in response to the subpoena is ongoing.

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 with certainty 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.

Constitutional Reform of the Kingdom of the Netherlands; Dissolution of the Netherlands Antilles

We were organized under the laws of the Netherlands Antilles in 1987, with our principal executive offices located on the island of Curaçao. Prior to October 10, 2010, the Netherlands Antilles, together with Aruba and the Netherlands, formed the Kingdom of the Netherlands, with Curaçao being an island territory of the Netherlands Antilles. Under a constitutional reform of the Kingdom of the Netherlands, agreed upon among the Netherlands Antilles, Aruba and the Netherlands, the Netherlands Antilles was dissolved effective October 10, 2010. Also effective October 10, 2010, Curaçao became an individual constitutional entity within the Kingdom of the Netherlands, having its own government and laws. As a result of the constitutional reform and the dissolution of the Netherlands Antilles, the Netherlands Antilles law ceased to exist and Orthofix is now a Curaçao legal entity subject to Curaçao law. Although Curaçao has become a separate and autonomous country with its own laws and regulations, the civil and corporate Netherlands Antilles law as they applied to Orthofix before October 10, 2010, did not change under the constitutional reform. In effect, Curaçao has adopted the Netherlands Antilles civil and corporate law (to which Orthofix was subject) that was in effect prior to October 10, 2010.

Table of Contents

Item 1A. Risk Factors

The following risk factor should be read in conjunction with the other risk factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (the Form 10-K), as supplemented by the risk factors discussed in Part II, Item 1A. Risk Factors in our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2010, as well as the other disclosures contained in this Form 10-Q.

Provisions of Curaçao law may have adverse consequences for our shareholders.

We were organized under the laws of the Netherlands Antilles in 1987, with our principal executive offices located on the island of Curaçao. Prior to October 10, 2010, the Netherlands Antilles, together with Aruba and the Netherlands, formed the Kingdom of the Netherlands, with Curaçao being an island territory of the Netherlands Antilles. Under a constitutional reform of the Kingdom of the Netherlands, agreed upon among the Netherlands Antilles, Aruba and the Netherlands, the Netherlands Antilles was dissolved effective October 10, 2010. Also effective October 10, 2010, Curaçao became an individual constitutional entity within the Kingdom of the Netherlands, having its own government and laws. As a result of the constitutional reform and the dissolution of the Netherlands Antilles, the Netherlands Antilles law ceased to exist and Orthofix is now a Curaçao legal entity subject to Curaçao law. Although Curaçao has become a separate and autonomous country with its own laws and regulations, the civil and corporate Netherlands Antilles law as they applied to Orthofix before October 10, 2010, did not change under the constitutional reform. In effect, Curaçao has adopted the Netherlands Antilles civil and corporate law (to which Orthofix was subject) that was in effect prior to October 10, 2010.

Our corporate affairs are therefore now governed by our Articles of Association and the corporate law of Curaçao as laid down in Book 2 of the Curaçao Civil Code (CCC). Although certain of the provisions of the CCC resemble certain of the provisions of the corporation laws of a number of states in the U.S., principles of law relating to such matters as the validity of corporate procedures, the fiduciary duties of management and the rights of our shareholders may differ from those that would apply if Orthofix were incorporated in a jurisdiction within the U.S. For example, there is no statutory right of appraisal under Curaçao corporate law, nor is there a right for shareholders of a Curaçao corporation to sue a corporation derivatively. In addition, we have been advised by Curaçao counsel that it is unlikely that (1) the courts of Curaçao would enforce judgments entered by U.S. courts predicated upon the civil liability provisions of the U.S. federal securities laws and (2) actions can be brought in Curaçao in relation to liabilities predicated upon the U.S. federal securities laws.

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

Exhibit	Description
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 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2010 and incorporated herein by reference).
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).

Table of Contents

- 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).
- 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 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).
- 10.12 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).
- 10.13 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).
- 10.14 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).
- 10.15 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).
- 10.16 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).
- 10.17 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).
- 10.18 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).

Table of Contents

- 10.19 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).
- 10.20 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).
- 10.21 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).
- 10.22 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).
- 10.23 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).
- 10.24 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).
- 10.25 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).
- 10.26 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).
- 10.27 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).
- 10.28 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).
- 10.29 Amended and Restated Employment Agreement, entered into and effective as of July 28, 2010, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's current report on Form 8-K filed August 3, 2010 and incorporated herein by reference).

Table of Contents

- 10.30 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).
- 10.31 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).
- 10.32 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).
- 10.33 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).
- 10.34 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).
- 10.35 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).
- 10.36 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).
- 10.37 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).
- 10.38 Amended and Restated Employment Agreement, entered into on July 28, 2010, by and between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company's current report on Form 8-K filed August 3, 2010 and incorporated herein by reference).
- 10.39 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).
- 10.40+ 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).

Table of Contents

- 10.41 Credit Agreement, dated as of August 30, 2010, among Orthofix Holdings, Inc., Orthofix International N.V. and certain domestic subsidiaries of Orthofix International N.V., the several banks and other financial institutions as may from time to time become parties thereunder, and JPMorgan Chase, N.A. (filed as an exhibit to the Company's current report on Form 8-K filed August 31, 2010 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: October 28, 2010

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

Date: October 28, 2010

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