

ORTHOFIX INTERNATIONAL N V

Form 10-Q

October 31, 2011

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, 2011

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

Curaçao
(Address of principal executive offices)

Not applicable
(I.R.S. Employer
Identification No.)

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

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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, a non-accelerated filer, or smaller reporting company. See definition of large accelerated filer, accelerated filer, non-accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large Accelerated filer Accelerated filer

Non-Accelerated filer (Do not check if a smaller reporting company) Smaller Reporting Company

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 25, 2011, 18,411,073 shares of common stock were issued and outstanding.

Table of Contents**Table of Contents**

	Page
PART I	
<u>FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2011 (unaudited) and December 31, 2010</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2011 and 2010 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and 2010 (unaudited)</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	25
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	38
Item 4. <u>Controls and Procedures</u>	39
PART II	
<u>OTHER INFORMATION</u>	40
Item 1. <u>Legal Proceedings</u>	40
Item 1A. <u>Risk Factors</u>	45
Item 6. <u>Exhibits</u>	46
<u>SIGNATURES</u>	51

Forward-Looking Statements

This Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, relating to our business and financial outlook, 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, or the risk factors described in Item 1A under the heading "Risk Factors," to reflect new information, the occurrence of future events or circumstances or otherwise.

The forward-looking statements in this filing do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to the expected sales of our products, including recently launched products, unanticipated expenditures, the resolution of pending litigation matters (including the government investigation relating to our bone growth stimulation business and the possible violations of the FCPA by our former Mexican orthopedic distribution entity, as well as certain product liability claims against our sports medicine global business unit), changing relationships with customers, suppliers, strategic partners and lenders, changes to and the interpretation of governmental regulations, ongoing 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 Item 1A. under the heading "Risk Factors" in this Form 10-Q and those set forth in our Annual Statement on Form 10-K for the year ended December 31, 2010 and our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011, under Item 1A., "Risk Factors."

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, 2011 (unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	\$ 29,020	\$ 13,561
Restricted cash	37,222	22,944
Trade accounts receivable, less allowance for doubtful accounts of \$7,621 and \$7,250 at September 30, 2011 and December 31, 2010, respectively	142,197	134,184
Inventories, net	94,707	84,589
Deferred income taxes	19,342	17,422
Escrow receivable	15,523	14,937
Prepaid expenses and other current assets	21,718	24,123
Total current assets	359,729	311,760
Property, plant and equipment, net	49,302	45,535
Patents and other intangible assets, net	38,938	41,457
Goodwill	179,796	176,497
Deferred income taxes	16,170	16,175
Other long-term assets	12,138	12,565
Total assets	\$ 656,073	\$ 603,989
Liabilities and shareholders equity		
Current liabilities:		
Bank borrowings	\$ 1,284	\$ 3,812
Current portion of long-term debt	15,000	7,500
Trade accounts payable	17,816	19,796
Accrued charges related to U.S. Government inquiries	46,000	
Other current liabilities	57,208	52,418
Total current liabilities	137,308	83,526
Long-term debt	197,445	208,695
Deferred income taxes	7,286	8,102
Other long-term liabilities	3,091	2,775
Total liabilities	345,130	303,098
Contingencies (Note 17)		
Shareholders equity:		
Common shares \$0.10 par value; 50,000,000 shares authorized; 18,411,073 and 17,726,645 issued and outstanding as of September 30, 2011 and December 31, 2010, respectively	1,841	1,772
Additional paid-in capital	220,639	195,402
Retained earnings	84,862	98,327
Accumulated other comprehensive income	3,601	5,390
Total shareholders equity	310,943	300,891

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

Total liabilities and shareholders' equity	\$ 656,073	\$ 603,989
--	------------	------------

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, 2011 and 2010**

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net sales	\$ 144,747	\$ 138,906	\$ 427,462	\$ 420,573
Cost of sales	36,029	32,266	104,082	99,046
Gross profit	108,718	106,640	323,380	321,527
Operating expenses				
Sales and marketing	57,615	57,281	171,412	170,756
General and administrative	20,214	21,568	67,123	63,410
Research and development	6,555	7,375	19,373	23,272
Amortization of intangible assets	1,319	1,402	3,947	4,259
Net gain on sale of vascular operations (Note 16)		20		(12,319)
Charges related to U.S. Government inquiries (Note 17)			46,000	
	85,703	87,646	307,855	249,378
Operating income	23,015	18,994	15,525	72,149
Other income (expense)				
Interest expense, net	(2,267)	(3,481)	(6,881)	(14,772)
Loss on refinancing of credit facility		(550)		(550)
Gain on interest rate swap				1,254
Other expense	(368)	(674)	(1,753)	(904)
	(2,635)	(4,705)	(8,634)	(14,972)
Income before income taxes	20,380	14,289	6,891	57,177
Income tax expense	(8,002)	(5,769)	(20,356)	(20,933)
Net income (loss)	\$ 12,378	\$ 8,520	(\$ 13,465)	\$ 36,244
Net income (loss) per common share:				
Basic	\$ 0.67	\$ 0.48	(\$ 0.74)	\$ 2.06
Diluted	\$ 0.66	\$ 0.48	(\$ 0.74)	\$ 2.03
Weighted average number of common shares:				
Basic	18,384,451	17,626,319	18,146,076	17,565,414
Diluted	18,850,625	17,836,537	18,146,076	17,824,273

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, 2011 and 2010**

(Unaudited, U.S. Dollars, in thousands)	Nine Months Ended September 30,	
	2011	2010
Cash flows from operating activities:		
Net (loss) income	(\$ 13,465)	\$ 36,244
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	17,276	15,510
Amortization of debt costs	938	215
Provision for doubtful accounts	7,057	5,901
Deferred income taxes	(2,305)	(2,767)
Share-based compensation	5,358	7,124
Provision for inventory obsolescence	3,465	5,872
Loss on refinancing of credit facility		550
Gain on interest rate swap		(1,254)
Net gain on sale of vascular operations		(12,319)
Tax benefit on non-qualified stock options	(1,575)	(1,859)
Other	1,304	507
Change in operating assets and liabilities, net of effect of sale of vascular operations and acquisitions:		
Trade accounts receivable	(15,746)	(10,080)
Inventories	(14,510)	667
Prepaid expenses and other current assets	1,869	(4,810)
Trade accounts payable	(2,180)	(5,072)
Charges related to U.S. Government inquiries	46,000	
Other current liabilities	6,110	(4,678)
Net cash provided by operating activities	39,596	29,751
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(16,826)	(16,831)
Capital expenditures for intangible assets	(495)	(329)
Payment made in connection with acquisition	(5,250)	
Net proceeds from sale of vascular operations		24,215
Net cash (used in) provided by investing activities	(22,571)	7,055
Cash flows from financing activities:		
Net proceeds from issuance of common shares	18,890	7,031
Repayments of long-term debt	(3,750)	(29,961)
Payment of refinancing fees	(758)	(3,986)
Proceeds from (repayment of) bank borrowings, net	(2,642)	564
Change in restricted cash	(14,288)	(10,339)
Cash payment for purchase of minority interest in subsidiary	(517)	
Tax benefit on non-qualified stock options	1,575	1,859
Net cash used in financing activities	(1,490)	(34,832)
Effect of exchange rate changes on cash	(76)	(54)
Net increase in cash and cash equivalents	15,459	1,920
Cash and cash equivalents at the beginning of the period	13,561	13,328

Cash and cash equivalents at the end of the period	\$ 29,020	\$ 15,248
--	-----------	-----------

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

1. Description of business

Orthofix International N.V. (the Company) is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical equipment. During 2010, the Company was comprised of four reportable segments: Domestic, Spinal Implants and Biologics (formerly referred to as Blackstone), Breg and International. Beginning January 1, 2011, the Company began managing its business by its three global business units (GBUs) comprised of Spine, Orthopedics and Sports Medicine supported by Corporate activities. See Note 14 for a description of each GBU.

2. Summary of significant accounting policies

(a) 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, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. The balance sheet at December 31, 2010 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, 2010.

(b) Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation. The reclassifications have no effect on previously reported net earnings or shareholders' equity. Consistent with the December 31, 2010 presentation, the Company has reclassified its changes to restricted cash in the Condensed Consolidated Statements of Cash Flows from operating activities to financing activities for the nine months ended September 30, 2010. The Company deemed this as a more appropriate disclosure since the cash is restricted for use by only those parties included in the secured revolving credit facility and secured term loan facility entered into on August 30, 2010 (see Note 7). Net cash provided by operating activities was previously reported as \$19.4 million for the nine months ended September 30, 2010.

Beginning January 1, 2011, the Company began managing its business by its three GBUs comprised of Spine, Orthopedics and Sports Medicine. The Company has revised Note 14, *Business Segment Information*, to disclose the GBUs' net sales and operating income for the three and nine months ended September 30, 2010.

(c) Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates including those related to contractual allowances, doubtful accounts, inventories, taxes, shared-based compensation, potential goodwill and intangible asset impairment and loss provision for contingent liabilities. Actual results could differ from these estimates.

(d) Recently Issued Accounting Standards

On September 15, 2011 the FASB issued Accounting Standards Update (ASU) 2011-08, Testing Goodwill for Impairment (the revised standard). The revised standard is intended to reduce the cost and complexity of the annual goodwill impairment test by

Table of Contents

providing both public and nonpublic entities with the option of performing a qualitative assessment to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment test required under current accounting standards. The revised standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, with early adoption permitted for certain companies. The Company is currently assessing the potential impact the adoption of this ASU will have on its consolidated results of operations and consolidated financial position.

In July 2011, the FASB issued ASU 2011-07, *Health Care Entities (Topic 954)*, which requires healthcare organizations that perform services for patients for which the ultimate collection of all or a portion of the amounts billed or billable cannot be determined at the time services are rendered to present all bad debt expense associated with patient service revenue as an offset to the patient service revenue line item in the statement of operations. The ASU also requires qualitative disclosures about the Company's policy for recognizing revenue and bad debt expense for patient service transactions and quantitative information about the effects of changes in the assessment of collectability of patient service revenue. This ASU is effective for fiscal years beginning after December 15, 2011, and will be adopted by the Company in the first quarter of 2012. The Company is currently assessing the potential impact the adoption of this ASU will have on its consolidated results of operations and consolidated financial position.

On June 16, 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*. This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in shareholders' equity and provides for either a single continuous statement or two separate statements. Both options require companies to present the components of net income and total net income, the components of other comprehensive income along with a total for other comprehensive income. Companies are also required to present reclassification adjustments for items that are reclassified from other comprehensive income to net income within these statements. This standard will be applied retrospectively for fiscal years beginning after December 15, 2011 with early adoption permitted. The disclosure requirements of this standard will not have a material effect on the Company's results of operations or financial position as the amendment impacts presentation only.

3. 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 first in, first out (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. Consignment inventory represents immediately saleable finished products located at third party customers, such as distributors and hospitals.

Inventories were as follows:

(US\$ in thousands)	September 30, 2011	December 31, 2010
Raw materials	\$ 15,512	\$ 12,186
Work-in-process	6,907	5,855
Finished products	54,405	54,049
Field inventory	40,603	32,915
Consignment inventory	8,621	9,009
	126,048	114,014
Less reserve for obsolescence	(31,341)	(29,425)
	\$ 94,707	\$ 84,589

Table of Contents**4. Patents and other intangible assets**

(US\$ in thousands)	September 30, 2011	December 31, 2010
Cost		
Patents and developed technologies	\$ 26,607	\$ 26,226
Trademarks definite lived (subject to amortization)	592	543
Trademarks indefinite lived (not subject to amortization)	23,104	23,104
Contracts with insurers	1,000	
Distribution networks	44,586	44,586
	95,889	94,459
Accumulated amortization		
Patents and developed technologies	(19,870)	(18,267)
Trademarks definite lived (subject to amortization)	(375)	(337)
Contracts with insurers	(188)	
Distribution networks	(36,518)	(34,398)
	(56,951)	(53,002)
Patents and other intangible assets, net	\$ 38,938	\$ 41,457

The \$1 million of contracts with insurers relates to the Omni Motion, Inc. acquisition, which is discussed in further detail in Note 5. Amortization expense for intangible assets is estimated to be approximately \$2.6 million for the remainder of 2011 and \$5.2 million, \$2.3 million, \$1.8 million, \$1.2 million, \$1.0 million and \$1.7 million for the periods ending December 31, 2012, 2013, 2014, 2015 and 2016 and thereafter, respectively.

5. Goodwill

The following table presents the changes in the net carrying value of goodwill:

(US\$ in thousands)	Total
At December 31, 2010	\$ 176,497
Acquisitions	3,382
Foreign currency	(83)
At September 30, 2011	\$ 179,796

On February 17, 2011, the Company, through its wholly-owned subsidiary, Breg Holdings LLC, purchased 100% of the stock of Omni Motion, Inc. ("Omni Motion") for a cash purchase price of \$5.3 million plus acquisition costs. These acquisition costs have been recognized as general and administrative expenses in the 2011 condensed consolidated statements of operations. The acquisition and related costs were financed with cash on hand. With the acquisition of Omni Motion, the Company expanded its presence in the sports medicine industry and its ability to provide related billing services. The results of Omni Motion's operations have been included in the Company's consolidated results of operations from the date of acquisition. The purchase price has been allocated to assets acquired and liabilities assumed based on their estimated fair value at the acquisition date. The Company acquired \$1.5 million of tangible assets, \$1.0 million of definite lived intangible assets and assumed liabilities of \$0.6 million. The Company has recorded the excess purchase price of \$3.4 million to goodwill and is reflected in the Sports Medicine GBU. Proforma financial information is not required based on the materiality of the acquisition to the Company's condensed consolidated financial statements.

6. Bank borrowings

Borrowings under lines of credit consist of borrowings in Euros used to fund international operations. The borrowings under such facility were \$1.3 million and \$3.8 million at September 30, 2011 and December 31, 2010, respectively. The weighted average interest rates on borrowings under lines of credit as of September 30, 2011 and December 31, 2010 were 4.99% and 3.57%, respectively.

Table of Contents

The Company had unused available lines of credit of 6.3 million (\$8.5 million) at September 30, 2011 in its Italian lines of credit. These lines of credit are unsecured and provide the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

7. Long-term debt

On August 30, 2010, the Company's wholly-owned U.S. holding company, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a Credit Agreement (the 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.

The Credit Agreement provides 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). 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.

As of September 30, 2011 and December 31, 2010, the Company had \$95 million and \$98.8 million, respectively, outstanding under the Term Loan Facility and \$117.4 million outstanding under the Revolving Credit Facility. 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 Credit Agreement) plus an applicable margin (in each case subject to adjustment based on financial ratios). The 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 began on December 31, 2010 and end on December 31, 2015. Outstanding principal on the Revolving Credit Facility is due on December 31, 2015.

As of September 30, 2011 and December 31, 2010, the entire Term Loan Facility and \$100 million of the Revolving Credit Facility, was at the LIBOR rate plus a margin of 3.00%. The remaining \$17.4 million of the Revolving Credit Facility was at a base rate (as defined in the Credit Agreement) plus a margin of 2.00%. The effective interest rate on the Credit Facilities as of September 30, 2011 and December 31, 2010 was 3.4% in both dates.

The Credit Agreement requires Orthofix Holdings and the Company to comply with coverage ratios and contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. The 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. Management believes the Company was in compliance with the affirmative covenants at September 30, 2011.

In May 2011, the Company obtained an amendment to the Credit Agreement (the Amended Credit Agreement) to provide additional capacity under the various restrictive negative covenants for the payment by the Company of the Specified Settlement Amounts (as defined in the Amended Credit Agreement) associated with each of the potential settlements (see Note 17). The amendment updates the definition of Consolidated EBITDA to exclude Specified Settlement Amounts of up to \$50 million in the aggregate. As a result of the Amended Credit Agreement, management believes the Company was in compliance with the negative covenants at September 30, 2011 and there were no events of default. The Company expects to be in compliance with its covenants prospectively.

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, debt repayments and any payment by the Company of the Specified Settlement Amounts as described above. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of September 30, 2011 and December 31, 2010 was \$212.2 million and \$178.5 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities from access to cash held by Orthofix Holdings and its subsidiaries. The amount of restricted cash of the Company as of September 30, 2011 and December 31, 2010 was \$37.2 million and \$22.9 million, respectively.

Table of Contents

In conjunction with obtaining the Credit Facilities and the Amended Credit Agreement, the Company incurred debt issuance costs of \$5.0 million which includes \$0.8 million of costs related to the May 2011 amendment. These costs are being amortized using the effective interest method over the life of the Credit Facilities. As of September 30, 2011 and December 31, 2010, debt issuance costs, net of accumulated amortization, related to the Credit Agreement and the Amended Credit Agreement were \$3.8 million and \$3.9 million, respectively.

8. Derivative instruments

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 (loss).

(US\$ in thousands) As of September 30, 2011	Fair value: favorable (unfavorable)	Balance sheet location
Cross-currency swap	\$ 251	Other long-term assets
As of December 31, 2010		
Cross-currency swap	(\$ 262)	Other long-term liabilities

(US\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Interest rate swap gain recognized in net income (loss)	\$	\$	\$	\$ 1,254
Cross-currency swap unrealized gain (loss) recorded in other comprehensive income (loss), net of taxes	\$ (927)	\$ 773	\$ 374	\$ 579
<i>Cross-currency swap</i>				

In 2006, the Company entered into a cross-currency swap agreement with Wells Fargo 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 executing the Company's Credit Agreement (see Note 7), the Company terminated this cross-currency swap agreement on September 30, 2010. 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 then current fair value of the terminated cross-currency swap was an unfavorable \$450,000 (the cash settlement amount). The cash settlement amount paid to Wells Fargo was recorded in other long term assets on the condensed consolidated balance sheets and is being amortized over the remaining life of the underlying transaction, assuming such payments remain probable.

Under the terms of the replacement swap agreement, the Company pays Euros based on a \$38.3 million notional value and a fixed rate of 5.00% and receives U.S. dollars based on a notional value of \$52.0 million and a fixed rate of 4.635%. The expiration date is December 30, 2016, the date upon which the underlying intercompany debt, to which the replacement swap agreement applies, matures. The replacement swap agreement is designated as a cash flow hedge for which the Company records the effective portions of the change in fair value as unrealized gains (losses), net of tax, within other comprehensive income (loss).

Table of Contents*Interest rate swap*

In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company's 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, 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, which resulted in a \$1.3 million gain recognized for the nine months ended September 30, 2010.

9. Fair value measurements

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

- Level 1 quoted prices in active markets for identical assets and liabilities
- Level 2 observable inputs other than quoted prices in active markets for identical or similar assets and liabilities
- Level 3 unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

As of September 30, 2011, the Company held financial instruments including cash equivalents, restricted cash, accounts receivable, short-term bank borrowings, accounts payable, long-term secured debt and a cross-currency derivative contract. Cash equivalents, restricted cash, accounts receivable, short-term bank borrowings and accounts payable approximate fair value due to the short-term maturities of these instruments. The Credit Facilities carry a floating rate of interest, and therefore, the carrying value is considered to approximate the fair value.

The Company's cross-currency derivative instrument is the only financial instrument recorded at fair value on a recurring basis. This instrument consists of an over-the-counter 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 fair value measurement. 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 September 30, 2011	Level 1	Level 2	Level 3
Derivative financial instruments ⁽¹⁾				
Cash flow hedges				
Cross-currency hedge	\$ 251	\$ 0	\$ 251	\$ 0

(US\$ in thousands)	Balance December 31, 2010	Level 1	Level 2	Level 3
Derivative Financial Instruments ⁽¹⁾				
Cash Flow Hedges				
Cross currency hedge	\$ (262)	\$	\$ (262)	\$

(1) See Note 8.

Table of Contents**10. Comprehensive income (loss)**

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and the effective portion of the unrealized gain from the Company's cross-currency swap, which is designated and accounted for as a cash flow hedge (refer to Note 8). The components of and changes in accumulated other comprehensive income were as follows:

(US\$ in thousands)	Foreign Currency Translation Adjustments	Fair Value of Cross-Currency Swap	Accumulated Other Comprehensive Income
Balance at December 31, 2010	\$ 5,085	\$ 305	\$ 5,390
Unrealized gain on cross-currency swap, net of tax of \$216		374	374
Foreign currency translation adjustment ⁽¹⁾	(2,163)		(2,163)
Balance at September 30, 2011	\$ 2,922	\$ 679	\$ 3,601

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

Comprehensive income (loss) was comprised of the following components:

(US\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net income (loss)	\$ 12,378	\$ 8,520	\$ (13,465)	\$ 36,244
Other comprehensive income (loss):				
Unrealized gain (loss) on cross-currency swap, net of tax	(927)	773	374	579
Foreign currency translation adjustment	(5,787)	3,969	(2,163)	(1,324)
Total comprehensive income (loss)	\$ 5,664	\$ 13,262	\$ (15,254)	\$ 35,499

11. Earnings per share

For the three and nine months ended September 30, 2011 and 2010, there were no adjustments to net income (loss) for purposes of calculating basic and diluted net income (loss) available to common shareholders. The following is a reconciliation of the weighted average shares used in the basic and diluted net income (loss) per common share computations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Weighted average common shares-basic	18,384,451	17,626,319	18,146,076	17,565,414
Effect of dilutive securities:				
Unexercised stock options net of treasury share repurchase	466,174	210,218		258,859
Weighted average common shares-diluted	18,850,625	17,836,537	18,146,076	17,824,273

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

No adjustment has been made in the nine months ended September 30, 2011 for any common stock equivalents because their effects would be anti-dilutive. For the nine months ended September 30, 2011, potentially dilutive shares totaled 331,775.

Options to purchase shares of common stock with exercise prices in excess of the average market price of common shares are not included in the computation of diluted earnings per share. There were 787,440 and 2,600,874 outstanding options not included in

Table of Contents

the diluted earnings per share computation for the three and nine months ended September 30, 2011, respectively, because the inclusion of these options was anti-dilutive. There were 1,767,764 and 1,691,289 outstanding options not included, respectively, in the diluted earnings per share computation for the three and nine months ended September 30, 2010, respectively, because the inclusion of these options was anti-dilutive.

12. 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 condensed consolidated statements 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:

(US\$ in thousands)	Three Months		Nine Months Ended	
	Ended September 30, 2011	2010	September 30, 2011	2010
Cost of sales	\$ 45	\$ 81	\$ 124	\$ 272
Sales and marketing	449	807	1,608	2,697
General and administrative	836	753	3,494	3,900
Research and development	31	35	132	255
Total	\$ 1,361	\$ 1,676	\$ 5,358	\$ 7,124

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

During the three and nine months ended September 30, 2011, there were 169,110 and 684,428 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the three and nine months ended September 30, 2010, there were 39,764 and 518,292 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

13. Income taxes

The Company recognized a \$20.4 million provision for income tax for the nine months ended September 30, 2011. This reflects a disproportionate ratio to the \$6.9 million of income before tax, as the Company has not recorded a tax benefit associated with the expense attributable to the charges related to U.S. Government inquiries due to the uncertainty of the extent to which these expenses will be deductible for income tax purposes. A formal analysis of final settlement documents will be required to determine the nature and extent of the anticipated tax deductions if any. The effective tax rate for the first nine months of 2011 was 38.5% excluding the impact of the discrete charges related to the U.S. Government inquiries for which no benefit was recorded. The effective tax rate of 36.6% 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. Excluding the sale of the Company's vascular operations, the Company's effective tax rate would have been approximately 38.9% for the first nine months of 2010. The difference between the 38.5% and the 38.9% is driven by the Company's mix of earnings among various tax jurisdictions, state taxes and current period losses in certain foreign jurisdictions for which the Company does not currently provide a tax benefit.

As of September 30, 2011 and December 31, 2010, the Company's gross unrecognized tax benefit, inclusive of interest and penalties, was \$1 million. 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, 2011 and December 31, 2010, the Company had approximately \$0.4 million accrued for payment of interest and penalties. All of the unrecognized tax benefits 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

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 federal tax authorities is closed for years prior to December 31, 2008. The statute of limitations for the various state tax filings is closed in most instances for years prior to December 31, 2007. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to December 31, 2006.

14. Business segment information

The Company's segment information is prepared on the same basis that management reviews the financial information for operational decision making purposes. Beginning January 1, 2011, the Company began managing its business by its three GBUs, which are comprised of Spine, Orthopedics and Sports Medicine supported by Corporate activities. These GBUs represent the current segments for which the Company's Chief Operating Decision Maker reviews financial information and makes resource allocation decisions among business units. Accordingly, the Company's segment information (as provided below) has been prepared based on the Company's three GBUs reporting segments. Prior year disclosures have been revised to conform to these new GBU reporting segments. These new segments are discussed below.

Spine

Spine provides a portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of spinal conditions. This global business unit specializes in the design, development and marketing of the Company's spinal implant products along with bone growth stimulation and biologics products used in spine applications. Spine distributes its products through a network of distributors, sales representatives and affiliates. This global business unit uses both direct and distributor sales representatives to sell spine products to hospitals, doctors, and other healthcare providers, globally.

Orthopedics

Orthopedics provides a comprehensive portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to spine. This global business unit specializes in the design, development and marketing of the Company's orthopedic implant products along with bone growth stimulation and biologics products used in orthopedic applications. Orthopedics distributes its products through a network of distributors, sales representatives and affiliates. This global business unit uses both direct and distributor sales representatives to sell orthopedics products to hospitals, doctors, and other healthcare providers globally.

Sports Medicine

Sports Medicine designs, manufactures and distributes a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Sports Medicine distributes products through a network of domestic and international distributors, sales representatives, and affiliates to hospitals, doctors and other healthcare providers, primarily in the U.S.

Corporate

Corporate activities are comprised of the operating expenses of Orthofix International N.V. and its U.S. holding company subsidiary, Orthofix Holdings, Inc., along with activities not necessarily identifiable within the three GBUs.

Table of Contents*Segment Information*

The table below presents external net sales by market sector:

(US\$ in thousands)	External Net Sales by Market Sector Three Months Ended September 30,			
	2011	2010	Reported Growth	Constant Currency Growth
Spine Products				
Implants and Biologics	\$ 36,769	\$ 34,127	8%	8%
Stimulation	39,734	43,251	(8%)	(8%)
Total Spine Products	76,503	77,378	(1%)	(1%)
Orthopedics Products	40,803	35,116	16%	8%
Sports Medicine Products	25,561	23,689	8%	7%
Total Strategic Products	142,867	136,183	5%	3%
Divested Products ⁽¹⁾	1,880	2,723	(31%)	(31%)
Total Net Sales	\$ 144,747	\$ 138,906	4%	2%

(US\$ in thousands)	External Net Sales by Market Sector Nine Months Ended September 30,			
	2011	2010	Reported Growth	Constant Currency Growth
Spine Products				
Implants and Biologics	\$ 107,608	\$ 97,572	10%	10%
Stimulation	118,012	130,139	(9%)	(9%)
Total Spine Products	225,620	227,711	(1%)	(1%)
Orthopedics Products	121,416	110,834	10%	4%
Sports Medicine Products	75,492	70,439	7%	7%
Total Strategic Products	422,528	408,984	3%	2%
Divested Products ⁽¹⁾	4,934	11,589	(57%)	(57%)
Total Net Sales	\$ 427,462	\$ 420,573	2%	0%

- (1) Divested Products sales for the three and nine months ended September 30, 2011 include \$1.9 million and \$4.9 million, respectively, related to the vascular business which was divested in March 2010 (see Note 16). Divested Products sales for the three and nine months ended September 30, 2010 include \$1.9 million and \$6.6 million, respectively, related to the vascular business which was divested in March 2010 (see Note 16). This revenue represents amounts recognized in 2010 prior to the March 2010 sale date as well as revenue

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

generated in the three and nine months ended September 30, 2011 and 2010 from the transition services supply agreement that commenced upon the sale of the business. In addition, Divested Products sales for the three and nine months ended September 30, 2010 also include \$0.8 million and \$5.0 million related to the anesthesia product line, respectively. The Company exited its anesthesia product line after the expiration of its distribution agreement in the United Kingdom during the second quarter of 2010.

Table of Contents

The tables below reconcile net sales by market sector to the Company's GBU reporting segments:

(US\$ in thousands)	Sales by GBU for the Three Months Ended September 30, 2011			
	Spine	Orthopedics	Sports Medicine	Total
Spine Products				
Implants and Biologics	\$ 36,769	\$	\$	\$ 36,769
Stimulation	39,734			39,734
Total Spine Products	76,503			76,503
Orthopedics Products				
		40,803		40,803
Sports Medicine Products				
			25,561	25,561
Total Strategic Products	76,503	40,803	25,561	142,867
Divested Products			1,880	1,880
Total Net Sales	\$ 76,503	\$ 40,803	\$ 27,441	\$ 144,747

(US\$ in thousands)	Sales by GBU for the Three Months Ended September 30, 2010			
	Spine	Orthopedics	Sports Medicine	Total
Spine Products				
Implants and Biologics	\$ 34,127	\$	\$	\$ 34,127
Stimulation	43,251			43,251
Total Spine Products	77,378			77,378
Orthopedics Products				
		35,116		35,116
Sports Medicine Products				
			23,689	23,689
Total Strategic Products	77,378	35,116	23,689	136,183
Divested Products		822	1,901	2,723
Total Net Sales	\$ 77,378	\$ 35,938	\$ 25,590	\$ 138,906

Table of Contents

(US\$ in thousands)	Sales by GBU for the Nine Months Ended September 30, 2011			
	Spine	Orthopedics	Sports Medicine	Total
Spine Products				
Implants and Biologics	\$ 107,608	\$	\$	\$ 107,608
Stimulation	118,012			118,012
Total Spine Products	225,620			225,620
Orthopedics Products				
		121,416		121,416
Sports Medicine Products				
			75,492	75,492
Total Strategic Products	225,620	121,416	75,492	422,528
Divested Products			4,934	4,934
Total Net Sales	\$ 225,620	\$ 121,416	\$ 80,426	\$ 427,462

(US\$ in thousands)	Sales by GBU for the Nine Months Ended September 30, 2010			
	Spine	Orthopedics	Sports Medicine	Total
Spine Products				
Implants and Biologics	\$ 97,572	\$	\$	\$ 97,572
Stimulation	130,139			130,139
Total Spine Products	227,711			227,711
Orthopedics Products				
		110,834		110,834
Sports Medicine Products				
			70,439	70,439
Total Strategic Products	227,711	110,834	70,439	408,984
Divested Products		5,023	6,566	11,589
Total Net Sales	\$ 227,711	\$ 115,857	\$ 77,005	\$ 420,573

(US\$ in thousands)	Operating Income (Loss) by GBU		Three Months Ended		Nine Months Ended	
			September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Spine ⁽¹⁾			\$ 22,373	\$ 21,766	\$ 28,239	\$ 64,576
Orthopedics ⁽²⁾			4,501	(132)	5,842	3,717
Sports Medicine ⁽³⁾			(580)	3,078	35	19,598
Corporate ⁽⁴⁾			(3,279)	(5,718)	(18,591)	(15,742)
Total			\$ 23,015	\$ 18,994	\$ 15,525	\$ 72,149

(1) For the nine months ended September 30, 2011, the operating income for the Spine GBU included \$36.5 million of expenses in connection with charges related to U.S. Government inquiries.

(2)

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

For the nine months ended September 30, 2011, the operating income for the Orthopedics GBU included \$6.5 million of expenses in connection with charges related to U.S. Government inquiries.

- (3) For the three and nine months ended September 30, 2011, the operating income for the Sports Medicine GBU included \$2.5 million of litigation and settlement costs for certain product liability matters related to

Table of Contents

- our Sports Medicine GBU. For the nine months ended September 30, 2011, the operating income for the Sports Medicine GBU included \$2 million of insurance expense to cover additional product liability claims related to our Sports Medicine GBU. For the nine months ended September 30, 2010, the operating income for the Sports Medicine GBU included \$12.3 million from the net gain on sale of vascular operations (see Note 16). For the nine months ended September 30, 2010, the operating income for the Sports Medicine GBU included \$1.7 million of insurance expense to cover new product liability claims from its former pain management operations sold in 2008.
- (4) For the nine months ended September 30, 2011, the operating loss for the Corporate GBU included \$3 million of expenses in connection with charges related to U.S. Government inquiries and \$3.2 million of senior management succession charges.

15. Restructuring charges

In the fourth quarter of 2010, the Company initiated a reorganization plan to further streamline operations and lower operating costs within its Spine, Orthopedics and Sports Medicine GBUs. During the fourth quarter of 2010, the Company recorded restructuring charges of \$0.4 million in Spine and \$3.2 million in Orthopedics which were related to employee severance costs. Final cash payments were made during September 30, 2011 and no further charges are anticipated.

The following table presents changes in the restructuring liability, which is included within other current liabilities in the condensed consolidated balance sheets as of September 30, 2011 and December 31, 2010:

(US\$ in thousands)	Severance
Balance at December 31, 2010	\$ 1,638
Charges under 2010 plan	
Cash payments	(1,638)
Balance at September 30, 2011	\$

16. Sale of vascular operations

On March 8, 2010, the Company entered into an asset purchase agreement (the APA) in which the Company agreed to sell substantially all of its vascular operations related to the A-V IMPULSE SYSTEM® and related accessories (including finished products inventory and tangible assets). At the closing, the Company received payment of approximately \$27.7 million, which amount included the estimated value of certain finished products inventory conveyed at the closing and remains subject to post-closing verification.

Pursuant to the APA, the Company agreed to enter into certain transition arrangements at the closing, including (i) a transition services agreement pursuant to which, among other things, the Company agreed to 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 for 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). In September 2011 the Company completed an amendment to the supply agreement to supply certain ImPads until March 2014. The Company also agreed to enter into a five-year noncompetition agreement at closing with respect to the business of the assets being transferred. Due to the continuing contractual involvement of these agreements, the transaction did not meet the criteria for presentation as discontinued operations.

Table of Contents

The following table presents the value of the asset disposition, proceeds received, net of litigation settlement costs and net gain on sale of vascular operations as shown in the condensed consolidated statements of operations for the nine months ended September 30, 2010.

(US\$ in thousands)	Total
Cash proceeds, net of litigation ⁽¹⁾	\$ 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)
Net 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.

17. Contingencies

The Company is a party to outstanding legal proceedings, investigations and claims as described below. The Company believes that it is unlikely that the outcome of each of these matters, including the matters discussed below, will have a material adverse effect on the Company and its subsidiaries as a whole, notwithstanding that the unfavorable resolution of any matter may have a material effect on the Company's net earnings (if any) in any particular quarter. However, the Company cannot predict the outcome of any legal proceedings, investigations (including any settlement discussions with the government seeking to resolve such investigations) or claims made against it or its subsidiaries described in the paragraphs below, and there can be no assurance that the ultimate resolution of any such matter will not have a material adverse impact on the Company's consolidated financial position, results of operations, or cash flows.

The Company records accruals for certain of its outstanding legal proceedings, investigations or claims when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, the Company does not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then the Company discloses a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If the Company cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed.

The assessments whether a loss is probable or a reasonable possibility, and whether the loss or range of loss is reasonably estimable, often involve a series of complex judgments about future events. Among the factors that the Company considers in this assessment are the nature of existing legal proceedings, investigations and claims, the asserted or possible damages or loss contingency (if reasonably estimable), the progress of the matter, existing law and precedent, the opinions or views of legal counsel and other advisers, the involvement of the U.S. Government and its agencies in such proceedings, the Company's experience in similar matters and the experience of other companies, the facts available to the Company at the time of assessment, and how the Company intends to respond, or has responded, to the proceeding, investigation or claim. The Company's assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where the Company is not currently able to reasonably estimate a range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the matters are in the early stages, (iii) the matters involve novel or unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement have not reached the point where the Company believes a reasonable estimate of loss, or range of loss, can be made. In such instances, the Company believes that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

Table of Contents

In addition to the matters described in the paragraphs below, 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 reasonably estimable, the Company accrues appropriate amounts in the accompanying financial statements and provides disclosures as to the possible range of loss in excess of the amount accrued, if such range is reasonable estimable. As of September 30, 2011, the Company has recognized an aggregate accrual of \$1.5 million for such additional matters. The Company believes additional losses are individually and collectively immaterial as to a possible loss and range of loss.

Litigation

On or about July 23, 2007, the Company's 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. The Company is engaging in ongoing discussions with the government regarding the status, and possible resolution, of this matter. 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. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

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. The Company is engaging in ongoing discussions with the government regarding the status, and possible resolution, of this matter. 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 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 February 1, 2011, the parties further extended the tolling of the statute of limitations through and including May 31, 2011 with respect to any criminal proceedings that the government might later initiate. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

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 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 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

Table of Contents

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 understands that this lawsuit is related to the matters described above involving the U.S. Department of Health and Human Services, Office of the Inspector General, the U.S. Attorney's Office for the District of Massachusetts, and the U.S. Department of Justice. The Company has been vigorously defending against this lawsuit. 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 June 1, 2011, the United States Court of Appeals for the First Circuit reversed the motion to dismiss and remanded to the district court for further proceedings. In response to a joint motion to stay the action, on August 22, 2011, the United States District Court for the District of Massachusetts entered an order administratively closing the lawsuit for a period of no more than ninety (90) days. On August 30, 2011, Blackstone filed with the United States Supreme Court a Petition for a Writ of Certiorari to review the June 1, 2011 judgment of the United States Court of Appeals for the First Circuit. The Company is engaging in ongoing discussions with the government and counsel to the plaintiff relators regarding the status, and possible resolution, of this matter. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

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. The Company has responded to the subpoena. 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 the USAO-Nevada subpoena. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

On February 29, 2008, Blackstone received a Civil Investigative Demand (CID) from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. The 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. The Company understands that the CID and Ohio AG subpoena are related to the claims underlying the matters described above involving the U.S. Department of Health and Human Services, Office of the Inspector General, the U.S. Attorney's Office for the District of Massachusetts, and the U.S. Department of Justice. The Company has responded to the CID and the subpoena. 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 the Massachusetts CID and the Ohio AG subpoena. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with these matters.

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 alleged causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan and another provider. On September 19, 2011, Blackstone entered into settlement agreements with the plaintiff relators and the State of Arkansas resolving this matter. In addition, the Company and the representative of the former shareholders of Blackstone reached an agreement that all amounts payable under the settlement agreements would be paid out of the escrow fund established in connection with the Blackstone Merger Agreement, and, as of September 30, 2011, the amounts payable under these two settlement agreements have now been fully funded and paid from the escrow fund.

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, 2011, the escrow fund, which has subsequently accrued interest, contained \$49 million. The Company is also entitled to seek direct personal recourse against certain

Table of Contents

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 (September 22, 2012) 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 our condensed consolidated 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, 2011 and December 31, 2010, the escrow receivable was approximately \$15.5 million and \$14.9 million, respectively, 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 SofamorDanek 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 Degree Anterior Cervical Plate, Hallmark Anterior Cervical Plate, Reliant Cervical Plate, Pillar PEEK and Construx Mini PEEK VBR System products within the United States 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 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 the 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 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, December 16, 2009, October 13, 2010, October 14, 2010, October 18, 2010, December 3, 2010 and January 13, 2011, respectively. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. 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 and former employees in connection with its ongoing investigation. The Company has been cooperating, and intends to continue to cooperate, with the government's requests. In meetings with the Company and its attorneys regarding this matter, the Boston USAO 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

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 the Company, Orthofix Inc. 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 the court, the 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. On or about December 4, 2010, the U.S. District Court for the District of Massachusetts denied the Company's motion to dismiss.

On April 28, 2011, after a series of ongoing discussions and negotiations with the Boston USAO, our board of directors approved an agreement in principle proposed by the Boston USAO to resolve the criminal and civil matters described in the immediately preceding two paragraphs. We are currently in discussions with the Boston USAO, the United States Department of Justice (DOJ), and the Office of Inspector General of the Department of Health and Human Services (OIG), as to the final terms of a potential resolution of this matter. Based on information currently available, we believe that it is probable that a settlement with the U.S. Government will be reached and will, among other things, include monetary payments and certain related costs and expenses of approximately \$43.0 million. We have therefore recognized an accrual for this amount during the first quarter of 2011. There can be no assurance that we will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, we believe that the likelihood of any such additional material loss in excess of this amount is remote.

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. The complaint has been consolidated with the complaint described in the Bierman qui tam matter described above, and was unsealed on June 30, 2009. The Company was served with the complaint on or about September 9, 2009. With leave of the court, the relator filed a Second Amended Complaint on June 23, 2010 against the Company and against Orthofix Inc. 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 and 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. On or about November 4, 2010, the U.S. District Court for the District of Massachusetts granted in part and denied in part the Company's motion to dismiss. The court dismissed all claims against Orthofix Inc., and dismissed all claims against the Company except for Laughlin's employment retaliation claim. The court denied Laughlin's request to amend the complaint to attempt to re-assert the dismissed claims. Thereafter, the Company filed a motion for judgment on the pleadings with respect to the employment retaliation claim. On May 4, 2011 the court denied the Company's request to enter judgment in the Company's favor, but agreed that the complaint fails to satisfy the pleading requirements necessary to allege a retaliation claim against the Company. The court allowed Laughlin until May 18, 2011 to file an amended complaint with respect to this wrongful termination claim, in order to attempt to cure these deficiencies. Laughlin did not file an amended complaint and on June 20, 2011, the court granted the Company's motion for judgment on the pleadings and dismissed the case.

The Company's 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 is vigorously defending these cases. One of the Company's insurance carriers has asserted to the Company that certain potential losses related to this matter are not covered by the Company's insurance coverage, and the Company is discussing the matter with this carrier. The Company has recorded a \$0.9 million reserve associated with such matters. The Company currently cannot reasonably estimate any further possible loss, or range of loss, in connection with these matters.

Table of Contents

On or about August 2, 2010, Breg received a HIPAA subpoena issued by the U.S. Department of Justice (DOJ). 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. The Company believes that this subpoena relates to an investigation by DOJ into whether Breg's sale, marketing and labeling of local infusion pumps for pain management, prior to Breg's divestiture of this product line in 2008, complied with FDA regulations and federal law. The Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with this matter.

Breg is currently engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Beginning in 2010, several domestic product liability cases have been filed, mostly in California state court, alleging that the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units. These cases are at an early stage and no conclusion can be drawn at the present time regarding their potential outcome. However, the Company believes that meritorious defenses exist to these claims. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

During the second quarter of 2010 internal management review of Promeca S.A. de C.V. (Promeca), one of the Company's 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 healthcare entity. The Company engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation (the Promeca Internal Investigation) focusing on compliance with the Foreign Corrupt Practices Act (FCPA) and voluntarily contacted the Securities and Exchange Commission (the SEC) and the United States Department of Justice (DOJ) to advise both agencies that an internal investigation was underway. Promeca accounted for approximately one percent of the Company's consolidated net sales and consolidated total assets. On or about November 16, 2010, the Company received a subpoena from the SEC and DOJ seeking documents related to this matter. The Company has completed its production of documents to the SEC and DOJ in connection with the subpoena.

The Company completed the Promeca Internal Investigation in April 2011 and commenced settlement discussions with the U.S. Government regarding this matter on May 24, 2011. These discussions remain ongoing. The Company has established a \$3 million accrual in connection with the potential fines and penalties related to this matter. The Company's establishment of this accrual is based on, among other things, the results of its own internal investigation and an analysis of recent and similar FCPA resolutions. However, the Company is currently unable to assess whether the government will accept voluntary settlement terms that would be acceptable to the Company and that the Company could agree to without violating the terms of its credit agreement, as amended. Furthermore, the Company cannot currently assess the potential liability that might be incurred if a settlement is not reached and the government were to litigate the matter. As such, based on the information available at this time, any additional loss related to this matter is not reasonably estimable. The Company will continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government; actual liability could be higher than the amount accrued.

Table of Contents

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

The following discussion and analysis addresses our liquidity, financial condition and results of operations for the three and nine months ended September 30, 2011 compared to our results of operations for the three and nine months ended September 30, 2010. 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 Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

General Overview

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

We believe the keys to reaching our financial goals for 2011 include:

The successful introduction and market launch of new products across our three GBUs.

An enhancement to the coverage and quality of our distribution networks across all GBUs primarily in the U.S.

A decrease in operating expenses as a percentage of revenues as we continue to leverage our operating infrastructure against the increase in revenues noted above.

The successful navigation and potential resolution of our ongoing government investigation activities.

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

Our condensed consolidated financial statements include the financial results of our Company and our 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 U.S. Dollar. All foreign currency denominated 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 the translation of foreign currency are recorded in the accumulated other comprehensive income component of shareholders' equity. Transactional foreign currency gains and losses, including those generated from intercompany operations, are included in other expense, net on our condensed consolidated statements of operations and were \$(0.3) million and \$(1.5) million for the three and nine months ended September 30, 2011, respectively, as compared to \$(0.7) million for both the three and nine months ended September 30, 2010.

Our business is generally not seasonal in nature. 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. We do not consider the backlog of firm orders to be material. 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.

Table of Contents

Through December 31, 2010, we managed our operations as five reportable segments: Domestic, Spinal Implants and Biologics, Breg, International and Group. Beginning January 1, 2011, we began managing our business by our three GBUs, which are comprised of Spine, Orthopedics and Sports Medicine, supported by our Corporate activities. These GBUs represent the current segments in which our Chief Operating Decision Maker reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information (as provided below) has been prepared based on our three GBU reporting segments. Prior year disclosures have been revised to conform to these new GBU reporting segments. These new segments are discussed below. Corporate activities not necessarily identifiable within the three GBUs are recorded as part of Corporate. We have designated Presidents (or GBU leaders) to lead the various segments.

Spine

Spine provides a portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of spinal conditions. This global business unit specializes in the design, development and marketing of our spine implant products along with bone growth stimulation and biologics products used in spine applications. Spine distributes its products through a network of distributors, sales representatives and affiliates. This global business unit uses both direct and distributor sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.

Orthopedics

Orthopedics provides a comprehensive portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to spine. This global business unit specializes in the design, development and marketing of our orthopedic implant products along with bone growth stimulation and biologics products used in orthopedic applications. Orthopedics distributes its products through a network of distributors, sales representatives and affiliates. This global business unit uses both direct and distributor sales representatives to sell orthopedics products to hospitals, doctors and other healthcare providers, globally.

Sports Medicine

Sports Medicine designs, manufactures and distributes a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Sports Medicine distributes products through a network of domestic and international distributors, sales representatives and affiliates to hospitals, doctors and other healthcare providers, primarily in the U.S.

Corporate

Corporate activities are comprised of the operating expenses of Orthofix International N.V. and its U.S. holding company subsidiary, Orthofix Holdings, Inc., along with activities not necessarily identifiable with the three GBUs.

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

The following table displays net sales by market sector for the three and nine months ended September 30, 2011 and 2010. We assess our performance based on these GBUs and market sectors. We maintain our records and account for net sales, costs of sales and expenses by GBU.

(US\$ in thousands)	External Net Sales by Market Sector Three Months Ended September 30,			
	2011	2010	Reported Growth	Constant Currency Growth
Spine Products				
Implants and Biologics	\$ 36,769	\$ 34,127	8%	8%
Stimulation	39,734	43,251	(8%)	(8%)
Total Spine Products	76,503	77,378	(1%)	(1%)
Orthopedics Products				
Sports Medicine Products	25,561	23,689	8%	7%
Total Strategic Products	142,867	136,183	5%	3%
Divested Products ⁽¹⁾	1,880	2,723	(31%)	(31%)
Total Net Sales	\$ 144,747	\$ 138,906	4%	2%

(US\$ in thousands)	External Net Sales by Market Sector Nine Months Ended September 30,			
	2011	2010	Reported Growth	Constant Currency Growth
Spine Products				
Implants and Biologics	\$ 107,608	\$ 97,572	10%	10%
Stimulation	118,012	130,139	(9%)	(9%)
Total Spine Products	225,620	227,711	(1%)	(1%)
Orthopedics Products				
Sports Medicine Products	75,492	70,439	7%	7%
Total Strategic Products	422,528	408,984	3%	2%
Divested Products ⁽¹⁾	4,934	11,589	(57%)	(57%)
Total Net Sales	\$ 427,462	\$ 420,573	2%	%

- (1) Divested Products sales for the three and nine months ended September 30, 2011 include \$1.9 million and \$4.9 million, respectively, related to the vascular business which was divested in March 2010. Divested Products sales for the three and nine months ended September 30, 2010 include \$1.9 million and \$6.6 million, respectively, related to the vascular business which was divested in March

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

2010. This revenue represents amounts recognized in 2010 prior to the March 2010 sale date as well as revenue generated in the three and nine months ended September 30, 2010 and 2011 from the transition services supply agreement that commenced upon the sale of the business. In addition, Divested Products sales for the three and nine months ended September 30, 2010 also include \$0.8 million and \$5.0 million related to the anesthesia product line, respectively. The Company exited its anesthesia product line after the expiration of its distribution agreement in the United Kingdom during the second quarter of 2010.

Table of Contents

The tables below reconcile net sales by market sector to our GBU reporting segments:

(US\$ in thousands)	Sales by GBU for the Three Months Ended September 30, 2011			
	Spine	Orthopedics	Sports Medicine	Total
Spine Products				
Implants and Biologics	\$ 36,769	\$	\$	\$ 36,769
Stimulation	39,734			39,734
Total Spine Products	76,503			76,503
Orthopedics Products				
		40,803		40,803
Sports Medicine Products				
			25,561	25,561
Total Strategic Products	76,503	40,803	25,561	142,867
Divested Products			1,880	1,880
Total Net Sales	\$ 76,503	\$ 40,803	\$ 27,441	\$ 144,747

(US\$ in thousands)	Sales by GBU for the Three Months Ended September 30, 2010			
	Spine	Orthopedics	Sports Medicine	Total
Spine Products				
Implants and Biologics	\$ 34,127	\$	\$	\$ 34,127
Stimulation	43,251			43,251
Total Spine Products	77,378			77,378
Orthopedics Products				
		35,116		35,116
Sports Medicine Products				
			23,689	23,689
Total Strategic Products	77,378	35,116	23,689	136,183
Divested Products		822	1,901	2,723
Total Net Sales	\$ 77,378	\$ 35,938	\$ 25,590	\$ 138,906

Table of Contents

(US\$ in thousands)	Sales by GBU for the Nine Months Ended September 30, 2011			
	Spine	Orthopedics	Sports Medicine	Total
Spine Products				
Implants and Biologics	\$ 107,608	\$	\$	\$ 107,608
Stimulation	118,012			118,012
Total Spine Products	225,620			225,620
Orthopedics Products		121,416		121,416
Sports Medicine Products			75,492	75,492
Total Strategic Products	225,620	121,416	75,492	422,528
Divested Products			4,934	4,934
Total Net Sales	\$ 225,620	\$ 121,416	\$ 80,426	\$ 427,462

(US\$ in thousands)	Sales by GBU for the Nine Months Ended September 30, 2010			
	Spine	Orthopedics	Sports Medicine	Total
Spine Products				
Implants and Biologics	\$ 97,572	\$	\$	\$ 97,572
Stimulation	130,139			130,139
Total Spine Products	227,711			227,711
Orthopedics Products		110,834		110,834
Sports Medicine Products			70,439	70,439
Total Strategic Products	227,711	110,834	70,439	408,984
Divested Products		5,023	6,566	11,589
Total Net Sales	\$ 227,711	\$ 115,857	\$ 77,005	\$ 420,573

Table of Contents

The following table presents certain items from our condensed consolidated statements of operations as a percent of total net sales for the periods indicated:

	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
	(%)	(%)	(%)	(%)
Net sales	100	100	100	100
Cost of sales	25	23	24	24
Gross profit	75	77	76	76
Operating expenses:				
Sales and marketing	40	41	40	41
General and administrative	14	16	16	15
Research and development	5	5	5	6
Amortization of intangible assets	1	1	1	1
Net gain on sale of vascular operations	0	0	0	(3)
Charges related to U.S. Government inquiries	0	0	11	0
Operating income	16	14	4	17
Net income (loss)	9	6	(3)	9

Three Months Ended September 30, 2011 Compared to Three Months Ended September 30, 2010

Net sales increased \$5.8 million to \$144.7 million in the third quarter of 2011 compared to \$138.9 million for the same period last year. The impact of foreign currency increased sales by \$3.1 million during the third quarter of 2011 when compared to the third quarter of 2010.

Sales

Net sales in our Spine market sector decreased to \$76.5 million in the third quarter of 2011 compared to \$77.4 million for the same period last year, a decrease of 1%. The decrease in Spine's net sales was primarily the result of an 8% decrease in sales of our spine stimulation products in the third quarter of 2011 when compared to the same period in the prior year, due to lower industry-wide surgical procedures and organizational changes to our sales force. These sales decreases were partially offset by an 25% increase in sales of our biologics products and an increase in our hardware products of 3% when compared to the same period in the prior year. The improvement in hardware products included improved sales in our thoracolumbar devices for the third quarter of 2011 compared to the same period in the prior year due to increased sales of our Firebird platform products including Phoenix MIS and Deformity Correction.

Net sales in our Orthopedics market sector increased to \$40.8 million in the third quarter of 2011 compared to \$35.1 million for the same period last year, an increase of 16%. Orthopedics's constant currency net sales increased by 8%, or \$2.7 million, during the third quarter of 2011 as compared to the third quarter of 2010. This increase was led by hardware and the increased use of Trinity[®] Evolution in orthopedic applications but was offset by the reduction in stimulation products used in long-bone applications. Sales of our hardware products and biologics products increased 29% and 23%, respectively, during the third quarter of 2011 when compared with the same period last year.

Net sales in our Sports Medicine market sector increased to \$25.6 million in the third quarter of 2011 compared to \$23.7 million for the same period in the prior year, an increase of 8%. The third quarter of 2011 included revenues of \$1.2 million resulting from the acquisition of Omni Motion, Inc.

Net sales of our Divested Products for the three months ended September 30, 2011 and 2010 include \$1.9 million, in both periods, related to the vascular business which we divested in March 2010. This revenue represents amounts recognized in the third quarter 2010 and in 2011 from the transition services supply agreement that commenced upon the sale of the business. In addition, sales for the three months ended September 30, 2010 also include \$0.8 million related to the anesthesia product line. We exited the anesthesia product line after the expiration of our distribution agreement in the United Kingdom during the second quarter of 2010.

Table of Contents

Gross Profit Our gross profit increased \$2.1 million to \$108.7 million in the third quarter of 2011, compared to \$106.6 million for the same period last year. Gross profit as a percent of net sales in the third quarter of 2011 was 75.1% compared to 76.8% for the same period last year. The reduction in the gross profit margin is primarily a result of increased pricing pressures in the U.S. spinal implants and sports medicine markets, an unfavorable product and geographical sales mix and a negative impact of the change in foreign currency rates.

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 \$0.3 million, to \$57.6 million in the third quarter of 2011 compared to \$57.3 million in the third quarter of 2010. As a percent of net sales, sales and marketing expense was 39.8% and 41.2% in the third quarter of 2011 and 2010, respectively. This improvement is a result of the various consolidation and operational efficiency initiatives we have executed on over the past several quarters.

General and Administrative Expense General and administrative expense decreased \$1.4 million, or 6%, in the third quarter of 2011 to \$20.2 million compared to \$21.6 million in the third quarter of 2010. General and administrative expense as a percent of net sales was 14% in the third quarter of 2011 compared to 15.5% for the same period last year. The decrease is due to the various consolidation and operational efficiency initiatives we have executed on over the past several quarters. The third quarter of 2011 included \$2.5 million of litigation and settlement costs for certain product liability matters related to our Sports Medicine GBU. The third quarter of 2011 and 2010 included approximately \$1 million and \$3.7 million, respectively, 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.

Research and Development Expense Research and development expense decreased \$0.8 million in the third quarter of 2011 to \$6.6 million compared to \$7.4 million for the same period last year. As a percent of sales, research and development expense was 4.5% in the third quarter of 2011 compared to 5.3% for the same period last year. The decrease in research and development expenses in the third quarter of 2011 compared to the same period in the prior year was due to timing of spending related to our ongoing research, development and clinical activities, our focus to eliminate activities that are not directly related to developing and bringing our products to market, and certain improvements in our operational efficiencies.

Amortization of Intangible Assets Amortization of intangible assets decreased by \$0.1 million in the third quarter of 2011 to \$1.3 million compared to \$1.4 million for the same period last year.

Net Gain on Sale of Vascular Operations We recognized a net gain on sale of vascular operations of \$12.6 million in the first quarter of 2010 associated with the sale of our vascular operations related to the A-V IMPULSE SYSTEM® and related accessories on March 8, 2010. During the third quarter of 2010, we recorded an additional transaction related expense of \$0.2 million due to a revision in our estimated costs. No such gain or loss was recorded in the related quarters of 2011.

Interest Expense, net Interest expense, net was \$2.3 million for the third quarter of 2011 compared to \$3.5 million for the same period last year, primarily as the result of a lower rate of effective interest and a lower year over year outstanding debt balance.

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.

Other Expense Other expense was \$(0.4) million and \$(0.7) million for the third quarter of 2011 and 2010, respectively. The fluctuation can be mainly attributable to the effect of 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 before taxes was 39.3% and 40.4% during the third quarters of 2011 and 2010, respectively. The effective tax rate for the third quarter of 2011 and 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. The Company does 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.

Table of Contents

Net Income Net income for the third quarter of 2011 was \$12.4 million, or \$0.67 per basic and \$0.66 per diluted share, compared to net income of \$8.5 million, or \$0.48 per basic and diluted share for the same period last year.

Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2010

Net sales increased \$6.9 million to \$427.5 million for the first nine months of 2011 compared to \$420.6 million for the same period last year. The impact of foreign currency increased sales by \$6.7 million during the first nine months of 2011 when compared to the first nine months of 2010.

Sales

Net sales in our Spine market sector decreased to \$225.6 million in the first nine months of 2011 compared to \$227.7 million for the same period last year, a decrease of 1%. The decrease in Spine's net sales was primarily the result of a 9% decrease in sales of our spine stimulation products in the first nine months of 2011 when compared to the same period in the prior year, due to lower industry-wide surgical procedures and organizational changes to our sales force. These sales decreases were partially offset by a 22% increase in sales of our biologics products and an increase in our hardware products of 7% when compared to the same period in the prior year. The improvement in hardware products included improved sales in our thorocolumbar devices during the first nine months of 2011 compared to the same period in the prior year due to increased sales of our Firebird platform products including Phoenix MIS and Deformity Correction.

Net sales in our Orthopedics market sector increased to \$121.4 million in the first nine months of 2011 compared to \$110.8 million for the same period last year, an increase of 10%. Orthopedics's constant currency net sales increased by 4% or \$4.1 million, during the first nine months of 2011 as compared to the first nine months of 2010. This increase was led by hardware products and the increased use of Trinity[®] Evolution in orthopedic applications but was offset by the reduction in stimulation products used in long-bone applications. Sales of our hardware products and biologics products increased 19% and 32%, respectively, during the first nine months of 2011 when compared with the same period last year.

Net sales in our Sports Medicine market sector increased to \$75.5 million in the first nine months of 2011 compared to \$70.4 million for the same period in the prior year, an increase of 7%. The first nine months of 2011 included revenues of \$3 million resulting from the acquisition of Omni Motion, Inc. in February 2011. In addition, the increase in net sales was also due to improved performances of our bracing product lines.

Net sales of our Divested Products for the nine months ended September 30, 2011 and 2010 include \$4.9 million and \$6.6 million, respectively, related to the vascular business which we divested in March 2010. This revenue represents amounts recognized in 2010 prior to the March 2010 sale date as well as revenue generated in the first six months of 2010 and in the first nine months of 2011 from the transition services supply agreement that commenced upon the sale of the business. In addition, sales for the nine months ended September 30, 2010 also include \$5 million related to the anesthesia product line. We exited the anesthesia product line after the expiration of our distribution agreement in the United Kingdom during the first six months of 2010.

Gross Profit Our gross profit increased \$1.9 million to \$323.4 million in the first nine months of 2011, compared to \$321.5 million for the same period last year. Gross profit as a percent of net sales in the first nine months of 2011 was 75.7% compared to 76.4% for the same period last year. This reduction in the gross profit margin is primarily the result of an unfavorable product and geographical sales mix and, to a lesser extent, increased pricing pressures in the U.S. spinal implant and Sports Medicine markets. The reduction in the gross profit margin is primarily a result of increased pricing pressures in the U.S. spinal implants and sports medicine markets, an unfavorable product and geographical sales mix and a negative impact of the change in foreign currency rates.

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 \$0.6 million to \$171.4 million in the first nine months of 2011 compared to \$170.8 million in the first nine months of 2010. As a percent of net sales, sales and marketing expense was 40.1% and 40.6% in the first nine months of 2011 and 2010, respectively. This improvement is a result of the various consolidation and operational efficiency initiatives we have executed on over the past several quarters.

Table of Contents

General and Administrative Expense General and administrative expense increased \$3.7 million, or 5.9%, in the first nine months of 2011 to \$67.1 million compared to \$63.4 million in the first nine months of 2010. General and administrative expense as a percent of net sales was 15.7% in the first nine months of 2011 compared to 15.1% for the same period last year. The first nine months of 2011 included \$2.5 million of litigation and settlement costs for certain product liability matters related to our Sports Medicine GBU and \$3.2 million of senior management succession charges. The first nine months of 2011 and 2010 included the impact of approximately \$7.6 million and \$5 million, respectively, 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. These expenses were partially offset by the various consolidation and operational efficiency initiatives we have executed on over the past several quarters.

Research and Development Expense Research and development expense decreased \$3.9 million in the first nine months of 2011 to \$19.4 million compared to \$23.3 million for the same period last year. As a percent of sales, research and development expense was 4.5% in the first nine months of 2011 compared to 5.5% for the same period last year. The decrease in research and development expenses in the first nine months of 2011 compared to the same period in the prior year was due to timing of spending related to our ongoing research, development and clinical activities and the costs associated with the cancellation of the cervical disc clinical trial in 2010, our focus to eliminate activities, that are not directly related to developing and bringing our products to market, and certain improvements in our operational efficiencies. In addition, the 2010 period included costs associated with the cancellation of the cervical disc trial.

Amortization of Intangible Assets Amortization of intangible assets decreased \$0.3 million in the first nine months of 2011 to \$3.9 million compared to \$4.2 million for the same period last year.

Net Gain on Sale of Vascular Operations We recognized a net gain on sale of vascular operations of \$12.3 million in the nine months of 2010 associated with 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 2011.

Charges Related to U.S. Government Inquiries During the first nine months of 2011, we reached an agreement in principle with the U.S. Government to resolve criminal and civil matters related to the previously disclosed government investigations of our bone growth stimulation business. Based on information currently available, we believe that it is probable that a settlement with the U.S. Government will be reached and will, among other things, include monetary payments and certain related costs and expenses of approximately \$43 million. We recorded a charge for this amount during the first quarter of 2011. There can be no assurance that we will enter into a consensual resolution of this matter with the Boston USAO, DOJ, or OIG, or what the terms of any such resolution might be.

We also recorded a charge of \$3 million to establish an accrual in connection with the potential fines and penalties related to Foreign Corrupt Practices Act (FCPA) violations that we voluntarily reported to the U.S. Government in June 2010 concerning our former Mexican orthopedic distribution entity. We completed our Promeca Internal Investigation in April 2011 and have commenced potential settlement discussions with the U.S. government regarding this matter in May 2011. The establishment of this accrual is based on the results of our own internal investigation and an analysis of recent and similar FCPA resolutions. Further, based upon the information available at this time any additional loss related to this matter is not reasonably estimable. We will continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government; actual liability could be higher than the amount accrued.

Although neither of these matters has concluded, we believe that the costs for which the charges have been recognized during the first nine months of 2011 are probable of being incurred and paid during 2011. We have recorded these charges associated with the potential settlement costs as charges related to U.S. Government inquiries in our consolidated statements of operations.

Interest Expense, net Interest expense, net was \$6.9 million for the first nine months of 2011 compared to \$14.8 million for the same period last year, primarily as the result of a lower rate of effective interest and a lower year over year outstanding debt balance.

Loss on Refinancing of Credit Facility In 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.

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 our 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 resulting in a gain of \$1.3 million for the nine months ended September 30, 2010.

Other Expense Other expense was \$1.8 million and \$0.9 million for the nine months of 2011 and 2010, respectively. The increase can be mainly attributable to the effect of 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 The Company recognized a \$20.4 million provision for income tax for the nine months ended September 30, 2011. This reflects a disproportionate ratio to the \$6.9 million of income before tax, as the Company has not recorded a tax benefit associated with the expense attributable to the charges related to U.S. Government inquiries due to the uncertainty of the extent to which these expenses will be deductible for income tax purposes. A formal analysis of final settlement documents will be required to determine the nature and extent of the anticipated tax deductions if any. The effective tax rate for the first nine months of 2011 was 38.5% excluding the impact of the discrete charges related to the U.S. Government inquiries for which no benefit was recorded. The effective tax rate of 36.6% 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. Excluding the sale of the Company's vascular operations, the Company's effective tax rate would have been approximately 38.9% for the first nine months of 2010. The difference between the 38.5% and the 38.9% is driven by the Company's mix of earnings among various tax jurisdictions, state taxes and current period losses in certain foreign jurisdictions for which the Company does not currently provide a tax benefit.

Net Income (Loss) Net Income (Loss) for the first nine months of 2011 was (\$13.5) million, or (\$0.74) per basic and diluted share, compared to net income of \$36.2 million, or \$2.06 per basic and \$2.03 per diluted share for the same period last year.

Liquidity and Capital Resources

Cash and cash equivalents at September 30, 2011 were \$66.2 million, of which \$37.2 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$36.5 million at December 31, 2010, of which \$22.9 million was subject to certain restrictions under the senior secured credit agreement discussed below.

Net cash provided by operating activities was \$39.6 million and \$29.8 million for the nine months ended September 30, 2011 and 2010, respectively. Net cash provided by operating activities is comprised of net income (loss), non-cash items (including depreciation and amortization, provision for doubtful accounts, provision for inventory obsolescence, share-based compensation, deferred income taxes and net gain on sale of vascular operations) and changes in working capital. Net income decreased \$49.7 million to a net loss of (\$13.5) million for the nine months ended September 30, 2011 from net income of \$36.2 million for the comparable period in the prior year. Non-cash items for the nine months ended September 30, 2011 increased \$14 million to \$31.5 million compared to non-cash items of \$17.5 million in the same period of 2010 primarily as a result of the net gain on the sale of vascular operations of \$12.3 million. Working capital accounts consumed \$24 million of cash in both the nine months ended September 30, 2011 and 2010. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 90 days at September 30, 2011 and 88 days at September 30, 2010 and inventory turns of 1.5 times at both September 30, 2011 and 2010.

Table of Contents

Net cash used in investing activities was \$22.6 million for the nine months ended September 30, 2011 compared to net cash provided by investing activities of \$7.1 million for the nine months ended September 30, 2010. During the first quarter of 2010, we sold our vascular operations with cash proceeds, net of litigation settlement costs, for \$24.2 million. During the first quarter of 2011, we acquired 100% of the stock of Omni Motion, Inc. for a cash purchase price of \$5.3 million plus acquisition costs. During the nine months ended September 30, 2011 and 2010, we invested \$17.3 million and \$17.2 million in capital expenditures, respectively.

Net cash used in by financing activities was \$1.5 million for the nine months ended September 30, 2011 compared to net cash used in financing activities of \$34.8 million for the nine months ended September 30, 2010. During the nine months ended September 30, 2011, we repaid approximately \$3.8 million against the principal on our senior secured term loan compared to \$30 million during the nine months ended September 30, 2010 which was primarily funded with cash proceeds from the sale of our vascular operations. Our restricted cash balance usage increased \$4 million to \$14.3 million compared to a usage of \$10.3 million for the same period in 2010. During the nine months ended September 30, 2011 and 2010, we received proceeds of \$18.9 million and \$7 million, respectively, from the issuance of 684,428 shares and 518,292 shares, respectively, of our common stock related primarily to stock purchase plan issuances and stock option exercises.

On August 30, 2010, our wholly-owned U.S. holding company, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a Credit Agreement (the Credit Agreement) with certain of our domestic direct and indirect subsidiaries (the Guarantors), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto.

The 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). 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.

As of September 30, 2011 and December 31, 2010, we had \$95 million and \$98.8 million, respectively, outstanding under the Term Loan Facility and \$117.4 million outstanding under the Revolving Credit Facility. 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 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 began on December 31, 2010 and end on December 31, 2015. Outstanding principal on the Revolving Credit Facility is due on December 31, 2015.

As of September 30, 2011 and December 31, 2010, the entire Term Loan Facility of \$95 million and \$98.8 million, respectively, was at the LIBOR rate plus a margin of 3.00%. In addition, as of September 30, 2011 and December 31, 2010, \$100.0 million of the Revolving Credit Facility was at the LIBOR rate plus a margin of 3.00% and the remaining \$17.4 million of the Revolving Credit Facility was at a base rate (as defined in the Credit Agreement) plus a margin of 2.00%. The effective interest rate on the Credit Facilities as of September 30, 2011 and December 31, 2010 was 3.4% in both periods.

The Credit Agreement requires us and Orthofix Holdings to comply with coverage ratios on a consolidated basis. The Credit Agreement contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. We believe we were in compliance with the affirmative covenants at September 30, 2011. The 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 Credit Agreement, which could permit acceleration of the debt payments under the facility.

In May 2011, we obtained an amendment to the Credit Agreement (the Amended Credit Agreement) to provide additional capacity under the various restrictive negative covenants for the payment by us of the Specified

Table of Contents

Settlement Amounts (as defined in the Amended Credit Agreement) associated with each of the potential settlements related to U.S. Government inquiries. The amendment updates the definition of Consolidated EBITDA to exclude Specified Settlement Amounts of up to \$50 million in the aggregate. As a result of the Amended Credit Agreement, we continue to comply with the coverage ratios and the covenants set forth in the Amended Credit Agreement. We believe we were in compliance with these financial covenants as measured at September 30, 2011. As defined in the Amended Credit Agreement, our leverage ratio cannot exceed 3.25 and our fixed charge ratio must be greater than or equal to 1.25.

Certain of our subsidiaries have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Our domestic subsidiaries, as parties to the credit agreement, have access to these net assets for operational purposes, debt repayments and payment of Specified Settlement Amounts. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of September 30, 2011 and December 31, 2010 was \$212.2 million and \$178.5 million, respectively. In addition, the Credit Agreement restricts us and our subsidiaries that are not parties to the Credit Facilities from access to cash held by Orthofix Holdings and its subsidiaries. The amount of such restricted cash as of September 30, 2011 and December 31, 2010 was \$37.2 million and \$22.9 million, respectively.

In conjunction with obtaining the Credit Facilities and the amendment, we incurred debt issuance costs of \$5.0 million, which includes \$0.8 million of costs related to the May 2011 amendment and which are being amortized using the effective interest method over the life of the Credit Facilities. As of September 30, 2011 and December 31, 2010, debt issuance costs, net of accumulated amortization, related to the Credit Agreement and the amendment were \$3.8 million and \$3.9 million, respectively.

At September 30, 2011, we had outstanding borrowings of 1.0 million (\$1.3 million) and unused available lines of credit of approximately 6.3 million (\$8.5 million) under lines of credit established in Italy to finance the working capital of our Italian operations. The terms of the lines of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

We believe that current cash balances together with projected cash flows from operating activities, the availability of the \$82.6 million revolving credit facility, the available Italian lines of credit and our debt capacity are sufficient to cover the Specified Settlement Amounts, anticipated working capital and capital expenditure needs including research and development costs over the near term.

In the fourth quarter of 2010, we initiated a reorganization plan to further streamline operations and lower operating costs within our Spine, Orthopedics and Sports Medicine GBUs. During the year ended December 31, 2010, we recorded restructuring charges of \$0.4 million in Spine and \$3.2 million in Orthopedics which were related to employee severance costs. Final cash payments were made during September 30, 2011 and no further charges are anticipated.

The following table presents changes in the restructuring liability, which is included within other current liabilities in the condensed consolidated balance sheets as of September 30, 2011 and December 31, 2010:

(US\$ in thousands)	Severance
Balance at December 31, 2010	\$ 1,638
Charges under 2010 plan	
Cash payments	(1,638)
Balance at September 30, 2011	\$

On March 8, 2010, we entered into an asset purchase agreement (the APA) in which we agreed to sell substantially all of our vascular operations related to the A-V IMPULSE SYSTEM® and related accessories (including finished products inventory and tangible assets). At the closing, we received payment of approximately \$27.7 million, which amount included the estimated value of certain finished products inventory conveyed at the closing and remains subject to post-closing verification.

Pursuant to the APA, we agreed to enter into certain transition arrangements at the closing, including (i) a transition services agreement pursuant to which, among other things, we agreed to continue to provide operational

Table of Contents

support with respect to the transferred assets in certain jurisdictions for a period of up to five months, and (ii) two separate supply agreements for 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, we completed the transition services agreement and one of the supply agreements (which supplies the other products). In September 2011, the Company completed an amendment to the supply agreement to supply certain ImPads until March 2014. We also agreed to enter into a five-year noncompetition agreement at closing with respect to the business of the assets being transferred. Due to the continuing contractual involvement of these agreements, the transaction did not meet the criteria for presentation as discontinued operations.

The following table presents the value of the asset disposition, proceeds received, net of litigation settlement costs and net gain on sale of vascular operations as shown in the condensed consolidated statements of operations for the nine months ended September 30, 2010.

(US\$ in thousands)	Total
Cash proceeds, net of litigation ⁽¹⁾	\$ 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)
Net gain on sale of vascular operations, net of taxes	\$ 8,821

- (1) In conjunction with the sale of the vascular operations, we settled an outstanding litigation claim by the former patent holders for \$3.5 million.

During the second quarter of 2011, we reached an agreement in principle with the U.S. Attorney's Office for the District of Massachusetts (the Boston USAO) to resolve criminal and civil matters related to the previously disclosed government investigations of its bone growth stimulation business. We are currently in discussions with the Boston USAO, the United States Department of Justice (DOJ), and the Office of Inspector General of the Department of Health and Human Services (OIG), as to the final terms of a potential resolution of this matter. Based on information currently available, we believe that it is probable that a settlement with the U.S. Government will be reached and will, among other things, include monetary payments and certain related costs and expenses of approximately \$43.0 million. We recorded a charge for this amount during the first quarter of 2011. The final settlement is subject to the negotiation and execution of definitive agreements with the Boston USAO, the DOJ, and the OIG.

We also recorded a charge of \$3.0 million during the first quarter of 2011 to establish an accrual in connection with the potential fines and penalties related to possible Foreign Corrupt Practices Act (FCPA) violations that we voluntarily reported to the U.S. Government in June 2010 and concerning our former Mexican orthopedic distribution entity (Promeca). We completed our Promeca Internal Investigation in April 2011 and commenced potential settlement discussions with the U.S. Government regarding this matter in May 2011. The establishment of this accrual is based on the results of our own internal investigation and an analysis of recent and similar FCPA resolutions. Further, based upon the information available at this time any additional loss related to this matter is not reasonably estimable. We will continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government; actual liability could be higher than the amount accrued.

There can be no assurance that we will enter into a consensual resolution of either of these two matters, or what the final terms of any such resolutions might be.

Although neither of these matters has concluded, we believe that the costs for which the charges have been recognized during the first nine months of 2011 are probable of being incurred and paid during 2011. These amounts are included in charges related to U.S. Government inquiries in our condensed consolidated statements of operations and in accrued charges related to U.S. Government inquiries on our condensed consolidated balance sheet as of September 30, 2011. In May 2011, we obtained an amendment to the Credit Agreement to provide additional capacity under the various restrictive negative covenants for the payment by us of the costs and expenses associated with each of these

settlements. It is our intention to fund as much of the payment with cash-on-hand when the payments are due and draw any additional amounts from our revolving credit facility.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations and the cost of financing and yields on cash and short-term investments. We use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of September 30, 2011, we had a currency swap in place to minimize foreign currency exchange risk related to a 38.3 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 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, 2011, the entire Term Loan Facility of \$95 million and \$100 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00%. The remaining \$17.4 million of the Revolving Credit Facility is at a base (as defined in the Credit Agreement) plus a margin of 2.00%. These margins are adjusted based upon the measurement of the consolidated leverage ratio of our Company and our subsidiaries with respect to the immediately preceding four fiscal quarters. As of September 30, 2011, our effective interest rate on our Credit Facilities was 3.4%. Based on the balance outstanding under the Credit Facilities as of September 30, 2011, 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 \$2.1 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, 2011, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million (\$31.0 million). We recorded an unrealized foreign currency gain during the nine months ended September 30, 2011 of less than \$0.1 million related to this un-hedged long-term intercompany note, which resulted from the strengthening of the Euro against the U.S. dollar during the period. As this note is not expected to be repaid, we have considered such amounts to be permanently invested and therefore recorded such amount in accumulated other comprehensive income. For the nine months ended September 30, 2011, we recorded a foreign currency loss of \$1.5 million on our condensed consolidated statements 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, 2011 and 2010 by foreign currency exchange rate fluctuations with the weakening of the U.S. dollar against the local foreign currency 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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer and Senior Vice President of Finance, 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 Form 10-Q. Based upon that evaluation, our President and Chief Executive Officer and Chief Financial Officer and Senior Vice President of Finance concluded that, as of the end of the period covered by this Form 10-Q, 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, 2011 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents**PART II. OTHER INFORMATION****Item 1. Legal Proceedings**

We are a party to outstanding legal proceedings, investigations and claims as described below. We believe that it is unlikely that the outcome of each of these matters, including the matters discussed below, will have a material adverse effect on us and our subsidiaries as a whole, notwithstanding that the unfavorable resolution of any matter may have a material effect on our net earnings (if any) in any particular quarter. However, we cannot predict the outcome of any legal proceedings, investigations (including any settlement discussions with the government seeking to resolve such investigations) or claims made against us or our subsidiaries described in the paragraphs below, and there can be no assurance that the ultimate resolution of any such matter will not have a material adverse impact on our consolidated financial position, results of operations, or cash flows.

We record accruals for certain of our outstanding legal proceedings, investigations or claims when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, we do not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then we disclose a reasonable estimate of the possible loss, or range of loss, if such reasonable estimate can be made. If we cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed.

The assessments whether a loss is probable or a reasonable possibility, and whether the loss or range of loss is reasonably estimable, often involve a series of complex judgments about future events. Among the factors that we consider in this assessment are the nature of existing legal proceedings, investigations and claims, the asserted or possible damages or loss contingency (if reasonably estimable), the progress of the matter, existing law and precedent, the opinions or views of legal counsel and other advisers, the involvement of the U.S. Government and its agencies in such proceedings, our experience in similar matters and the experience of other companies, the facts available to us at the time of assessment, and how we intend to respond, or have responded, to the proceeding, investigation or claim. Our assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where we are not currently able to reasonably estimate a range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the proceedings are in the early stages, (iii) the matters involve novel or unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that are expected ultimately to be resolved through negotiation and settlement have not reached the point where we believe a reasonable estimate of loss, or range of loss, can be made. In such instances, we believe that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

In addition to the matters described in the paragraphs below, 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 reasonably estimable, the Company accrues appropriate amounts in the accompanying financial statements and provides disclosures as to the possible range of loss in excess of the amount accrued, if such range is reasonable estimable. As of September 30, 2011, the Company has recognized an aggregate accrual of \$1.5 million for such additional matters. The Company believes additional losses are individually and collectively immaterial as to a possible loss and range of loss.

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 us. We believe that the subpoena concerns the compensation of physician consultants and related matters. We are engaging in ongoing discussions with the government regarding the status, and possible resolution, of this matter. On September 17, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between us, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the "Blackstone Merger Agreement"), for any losses to us resulting from this matter. (Our indemnification rights under the Blackstone Merger Agreement are described further below). We were subsequently notified by legal counsel for the former shareholders that the representative of the

Table of Contents

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. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

On or about January 7, 2008, we received a federal grand jury subpoena from the U.S. Attorney's Office for the District of Massachusetts. The subpoena seeks documents from us for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerns the compensation of physician consultants and related matters, and further believe that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters. We are engaging in ongoing discussions with the government regarding the status, and possible resolution, of this matter. On September 18, 2008, we submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. On or about April 29, 2009, counsel received a HIPAA subpoena issued by the U.S. Department of Justice. The subpoena seeks documents from us for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerns the compensation of physician consultants and related matters, and further believe that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters, 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 February 1, 2011, the parties further extended the tolling of the statute of limitations through and including May 31, 2011 with respect to any criminal proceedings that the government might later initiate. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

On or about December 5, 2008, we obtained a copy of a qui tam complaint filed by Susan Hutcheson and Philip Brown against Blackstone and us 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 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), we submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. On 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. We understand that this lawsuit is related to the matters described above involving the U.S. Department of Health and Human Services, Office of the Inspector General, the U.S. Attorney's Office for the District of Massachusetts, and the U.S. Department of Justice. We have been vigorously defending against this lawsuit. 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 June 1, 2011, the United States Court of Appeals for the First Circuit reversed the motion to dismiss and remanded to the district court for further proceedings. In response to a joint motion to stay the action, on August 22, 2011, the United States District Court for the District of Massachusetts entered an order administratively closing the lawsuit for a period of no more than ninety (90) days. On August 30, 2011, Blackstone filed with the United States Supreme Court a Petition for a Writ of Certiorari to review the June 1, 2011 judgment of the United States Court of Appeals for the First Circuit. We are engaging in ongoing discussions with the government and counsel to the plaintiff relators regarding the status, and possible resolution, of this matter. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

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. We believe that the subpoena concerns payments or gifts made by Blackstone to certain physicians. We have responded to the subpoena. On September 18, 2008, we 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. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

Table of Contents

On February 29, 2008, Blackstone received a Civil Investigative Demand (CID) from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. The CID seeks documents for the period from March 2004 through the date of issuance of the CID, and we believe 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. We believe that the Ohio AG subpoena arises from a government investigation that concerns the compensation of physician consultants and related matters. We understand that the CID and Ohio AG subpoena are related to the claims underlying the matters described above involving the U.S. Department of Health and Human Services, Office of Inspector General, the U.S. Attorney's Office for the District of Massachusetts, and the U.S. Department of Justice. We have responded to the CID and the subpoena. On September 18, 2008, we 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 Massachusetts CID and the Ohio AG subpoena. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with these matters.

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 alleged causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan and another provider. On September 19, 2011, Blackstone entered into settlement agreements with the plaintiff relators and the State of Arkansas resolving this matter. In addition, we reached an agreement with the representative of the former shareholders of Blackstone that all amounts payable under the settlement agreements would be paid out of the escrow fund established in connection with the Blackstone Merger Agreement and, as of September 30, 2011, the amounts payable under these two settlement agreements have now been fully funded and paid from the escrow fund.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have agreed to indemnify us 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, 2011, the escrow fund, which has subsequently accrued interest, contained \$49 million. We are 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 (September 22, 2012) and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

In addition to the foregoing claims, we have 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 us, 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 we believe 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 us from the escrow fund is not certain and there can be no assurance that losses to us from these matters will not exceed the amount of the escrow fund. Expenses incurred by us relating to the above matters are recorded as an escrow receivable in the condensed consolidated financial statements to the extent we believe, among other things, that collection of the claims is reasonably assured. Expenditures related to such matters for which we believe collection is doubtful are recognized in earnings when incurred. As of September 30, 2011 and December 31, 2010, the escrow receivable was approximately \$15.5 million and \$14.9 million, respectively, 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, we record 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 SofamorDanek 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 Degree Anterior Cervical Plate, Hallmark Anterior Cervical Plate, Reliant Cervical Plate, Pillar PEEK and Construx Mini PEEK VBR System products within the United States 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 consolidated financial position, results of operations or cash flows. On July 20, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for the losses to us resulting from this matter. We were 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, we received a HIPAA subpoena (HIPAA subpoena) issued by the Boston USAO. The subpoena sought documents concerning, among other things, our promotion and marketing of our bone growth stimulator devices. The Boston USAO issued supplemental subpoenas seeking documents in this matter, dated September 21, 2009, December 16, 2009, October 13, 2010, October 14, 2010, October 18, 2010, December 3, 2010 and January 13, 2011, respectively. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. 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 us with grand jury subpoenas for the testimony of certain current and former employees in connection with its ongoing investigation. We have been cooperating, and intend to continue to cooperate, with the government's requests. In meetings with us and our attorneys regarding this matter, the Boston USAO informed us that it is investigating possible criminal and civil violations of federal law related to our promotion and marketing of our bone growth stimulator devices.

On or about April 14, 2009, we 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 us, Orthofix Inc. 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. We and Orthofix Inc. were served on or about September 8, 2009. With leave of the 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. We believe that this lawsuit is related to the matter described above involving the HIPAA subpoena. On or about December 4, 2010, the U.S. District Court for the District of Massachusetts denied our motion to dismiss.

On April 28, 2011, after a series of ongoing discussions and negotiations with the Boston USAO, our board of directors approved an agreement in principle proposed by the Boston USAO to resolve the criminal and civil matters described in the immediately preceding two paragraphs. We are currently in discussions with the Boston USAO, the United States Department of Justice (DOJ), and the Office of Inspector General of the Department of Health and Human Services (OIG), as to the final terms of a potential resolution of this matter. Based on information currently available, we believe that it is probable that a settlement with the U.S. Government will be reached and will, among other things, include monetary payments and certain related costs and expenses of approximately \$43.0 million. We have therefore recognized an accrual for this amount during the first quarter of 2011. There can be no assurance that we will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, we believe that the likelihood of any such additional material loss in excess of this amount is remote.

Table of Contents

On or about July 2, 2009, we 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 us. The complaint has been consolidated with the complaint described in the Bierman qui tam matter described above, and was unsealed on June 30, 2009. We were served with the complaint on or about September 9, 2009. With leave of the court, the relator filed a Second Amended Complaint on June 23, 2010 against us and against Orthofix Inc. 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 we promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products and provided physicians kickbacks in the form of free units, referral fees and fitting fees. The complaint also alleges that TRICARE has been reimbursing us for our Cervical Stim[®] product without approval to do so. On or about November 4, 2010, the U.S. District Court for the District of Massachusetts granted in part and denied in part our motion to dismiss. The court dismissed all claims against Orthofix Inc., and dismissed all claims against us except for Laughlin's employment retaliation claim. The court denied Laughlin's request to amend the complaint to attempt to re-assert the dismissed claims. Thereafter, we filed a motion for judgment on the pleadings with respect to the employment retaliation claim. On May 4, 2011 the court denied our request to enter judgment in our favor, but agreed that the complaint fails to satisfy the pleading requirements necessary to allege a retaliation claim against us. The court allowed Laughlin until May 18, 2011 to file an amended complaint with respect to this wrongful termination claim, in order to attempt to cure these deficiencies. Laughlin did not file an amended complaint and on June 20, 2011, the court granted our motion for judgment on the pleadings and dismissed the case.

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. We believe that meritorious defenses exist to these claims and Breg is vigorously defending these cases. One of our insurance carriers has asserted to us that certain potential losses related to this matter are not covered by our insurance coverage, and we are discussing the matter with this carrier. The Company has recorded a \$0.9 million reserve associated with such matters. We currently cannot reasonably estimate any further possible loss, or range of loss, in connection with these matters.

On or about August 2, 2010, Breg received a HIPAA subpoena issued by the U.S. Department of Justice (DOJ). The subpoena seeks documents from us and our subsidiaries for the period January 1, 2000 through the date of the subpoena. Document production in response to the subpoena is ongoing. We believe that this subpoena relates to an investigation by DOJ into whether Breg's sale, marketing and labeling of local infusion pumps for pain management, prior to Breg's divestiture of this product line in 2008, complied with FDA regulations and federal law. We currently cannot reasonably estimate any further possible loss, or range of loss, in connection with these matters.

Breg is currently engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Beginning in 2010, several domestic product liability cases have been filed, mostly in California state court, alleging that the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units. These cases are at an early stage and no conclusion can be drawn at the present time regarding their potential outcome. However, we believe that meritorious defenses exist to these claims. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

During the second quarter of 2010 internal management review of Promeca S.A. de C.V. (Promeca), one of our Mexican subsidiaries, we received allegations of improper payments, allegedly made by certain of Promeca's local employees in Mexico, to employees of a Mexican governmental healthcare entity. We engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation (the Promeca Internal Investigation) focusing on compliance with the Foreign Corrupt Practices Act (FCPA) and voluntarily contacted the Securities and Exchange Commission (the SEC) and the United States Department of Justice (DOJ) to advise both agencies that an internal investigation was underway. Promeca accounted for approximately one percent of our consolidated net sales and consolidated total assets. On or about November 16, 2010, we received a subpoena from the SEC and DOJ seeking documents related to this matter. The Company has completed its production of documents to the SEC and DOJ in connection with the subpoena.

We completed the Promeca Internal Investigation in April 2011 and commenced settlement discussions with the U.S. Government regarding this matter on May 24, 2011. These discussions remain ongoing. We have established a \$3 million accrual in connection with the potential fines and penalties related to this matter. Our establishment of

Table of Contents

this accrual is based on, among other things, the results of our own internal investigation and an analysis of recent and similar FCPA resolutions. However, the Company is currently unable to assess whether the government will accept voluntary settlement terms that would be acceptable to the Company and that the Company could agree to without violating the terms of its credit agreement, as amended. Furthermore, the Company cannot currently assess the potential liability that might be incurred if a settlement is not reached and the government were to litigate the matter. As such, based on the information available at this time any additional loss related to this matter is not reasonably estimable. We will continue to evaluate the accrual pending final resolution of the investigation and the related settlement discussions with the government; actual liability could be higher than the amount accrued.

ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors from the factors discussed in Part I, Item 1A. *Risk Factors* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011.

Table of Contents**Item 6. Exhibits**

Exhibit Number	Description
2.1	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).
2.2	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, OrthofixS.r.l., Orthofix S.A., IntaventOrthofix 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	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).
10.2	First Amendment to Credit Agreement, dated May 4, 2011, among Orthofix Holdings, Inc., a Delaware corporation, Orthofix International N.V. (Orthofix International), a Netherlands Antilles corporation, certain domestic direct and indirect subsidiaries of Orthofix International, JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lender parties thereto (filed as an exhibit to the Company's current report on Form 8-K filed May 5, 2011 and incorporated herein by reference).
10.3+	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).
10.4	Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.5	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 March 31, 2011 and incorporated herein by reference).
10.6	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).
10.7	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).

Table of Contents

- 10.8 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).
- 10.9 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).
- 10.10 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).
- 10.11 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).
- 10.12 Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants 3 year cliff vesting) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
- 10.13 Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2011 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).
- 10.14 Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (post-2010 grants vesting over 3 years) (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
- 10.15 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).
- 10.16 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).
- 10.17 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).
- 10.18 Inducement Grant Nonqualified Stock Option Agreement, dated April 1, 2011, between Orthofix International N.V. and Vicente Trelles (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).

Table of Contents

- 10.19 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).
- 10.20 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).
- 10.21 Form of Award Letter Regarding Special Retention Cash Bonus Award (filed as an exhibit to the Company's current report on Form 8-K/A filed on February 23, 2011 and incorporated herein by reference).
- 10.22 Description of Director Compensation Policy (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
- 10.23 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).
- 10.24 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).
- 10.25 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).
- 10.26 Letter Agreement, dated June 15, 2011, between Orthofix Inc., Orthofix International N.V. and Alan W. Milinazzo (filed as an exhibit to the Company's quarterly report on current report on Form 8-K filed June 16, 2011 and incorporated herein by reference).
- 10.27 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).
- 10.28 Addendum to Amended and Restated Employment Agreement, entered into as of March 9, 2011, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's quarterly report on current report on Form 8-K filed March 15, 2011 and incorporated herein by reference).
- 10.29 Amended and Restated Employment Agreement, dated as of June 15, 2011 and effective as of August 1, 2011, by and between Orthofix Inc., Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the Company's quarterly report on current report on Form 8-K filed June 16, 2011 and incorporated herein by reference).
- 10.30 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).

Table of Contents

10.31	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).
10.32	Amendment No. 2 to Amended and Restated Employment Agreement, dated as of October 1, 2011, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed October 4, 2011 and incorporated herein by reference).
10.33	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).
10.34	Amended and Restate Employment Agreement, entered into on February 11, 2011, 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, 2010 and incorporated herein by reference).
10.35	Employment Agreement, entered into on December 9, 2010, by and between Orthofix Inc. and Jeffrey M. Schumm (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.36	Employment Agreement, entered into as of March 2, 2011, by and between Orthofix Inc. and Brian McCollum (filed as an exhibit to the Company's quarterly report on current report on Form 8-K filed March 7, 2011 and incorporated herein by reference).
10.37	Employment Agreement, entered into as of April 1, 2011, by and between Orthofix Inc. and Vicente Trelles (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
10.38 *	Employment Agreement, entered into as of October 1, 2011, by and between Orthofix Inc. and Bryan McMillan.
10.39	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).
10.40	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).
10.41	Separation Letter Agreement, dated February 7, 2011, between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company's current report on Form 8-K filed on February 10, 2011 and incorporated herein by reference).
10.42	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).
10.43	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).
10.44	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).

Table of Contents

- 10.45 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).
- 10.46 Amended and Restated Employment Agreement, entered into on July 1, 2009, by and between Orthofix Inc. and Eric Brown (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
- 10.47 Separation Letter Agreement, dated January 10, 2011, between Orthofix Inc. and Eric Brown (filed as an exhibit to the Company's current report on Form 8-K filed January 14, 2011 and incorporated herein by reference).
- 10.48 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).
- 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.
- 101* The following materials from the Orthofix International N.V. Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) related notes, tagged as blocks of text.

* 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 Section 13 or 15(d) 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 31 , 2011

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

Date: October 31, 2011

By: /s/ Brian McCollum
Name: Brian McCollum
Title: Chief Financial Officer and Senior Vice President of Finance