

ORTHOFIX INTERNATIONAL N V

Form 10-Q

November 06, 2009

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, 2009
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.
Commission File Number: 0-19961
ORTHOFIX INTERNATIONAL N.V.
(Exact name of registrant as specified in its charter)

Netherlands Antilles

N/A

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

7 Abraham de Veerstraat
Curaçao
Netherlands Antilles

N/A

(Address of principal executive offices)

(Zip Code)

599-9-4658525

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant 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 a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a 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 November 1, 2009, 17,135,398 shares of common stock were issued and outstanding.

Table of Contents

PART I FINANCIAL INFORMATION

<u>Item 1. Condensed Consolidated Financial Statements</u>	3
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	37
<u>Item 4. Controls and Procedures</u>	38

PART II OTHER INFORMATION

<u>Item 1. Legal Proceedings</u>	39
<u>Item 1A. Risk Factors</u>	42
<u>Item 6. Exhibits</u>	43
<u>SIGNATURES</u>	48

Exhibit 10.17

Exhibit 10.37

Exhibit 10.39

Exhibit 10.41

Exhibit 10.42

Exhibit 10.44

Exhibit 31.1

Exhibit 31.2

Exhibit 32.1

Exhibit 32.2

Forward-Looking Statements

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

Factors that could cause actual results to differ materially from those indicated by the forward-looking statements or that could contribute to such differences include, but are not limited to, risks relating to the expected sales of products, including recently launched products, unanticipated expenditures, changing relationships with customers, suppliers, strategic partners and lenders, unfavorable results in litigation matters, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, changes to and interpretation of governmental regulation of medical devices, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry and the economy, currency or interest rate fluctuations, corporate development and marketing development activities, including acquisitions and

divestitures, unexpected costs or operating unit performance related to recent acquisitions, unexpected difficulties meeting covenants under our senior secured bank credit facility and the other risks described under Item 1A Business Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and Part II, Item 1A Risk Factors in this Form 10-Q.

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

	September 30, 2009	December 31, 2008
(US Dollars, in thousands except share data)		
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,800	\$ 14,594
Restricted cash	13,218	10,998
Trade accounts receivable, less allowance for doubtful accounts of \$7,329 and \$6,473 at September 30, 2009 and December 31, 2008, respectively	127,359	110,720
Inventories, net	101,016	91,185
Deferred income taxes	20,497	17,543
Prepaid expenses and other current assets	34,426	29,610
Total current assets	303,316	274,650
Investments, at cost	345	2,095
Property, plant and equipment, net	37,559	32,660
Patents and other intangible assets, net	49,304	53,546
Goodwill	185,208	182,581
Deferred taxes and other long-term assets	13,046	15,683
Total assets	\$ 588,778	\$ 561,215
Liabilities and shareholders equity		
Current liabilities:		
Bank borrowings	\$ 3,689	\$ 1,907
Current portion of long-term debt	3,336	3,329
Trade accounts payable	27,188	23,865
Other current liabilities	61,540	45,894
Total current liabilities	95,753	74,995
Long-term debt	255,049	277,533
Deferred income taxes	3,252	4,509
Other long-term liabilities	7,436	2,117
Total liabilities	361,490	359,154
Contingencies (Note 19)		
Shareholders equity:		
Common shares \$0.10 par value; 50,000,000 shares authorized; 17,130,798 and 17,103,142 issued and outstanding as of September 30, 2009 and December 31, 2008, respectively	1,713	1,710
Additional paid-in capital	174,288	167,818
Retained earnings	44,658	29,647

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

Accumulated other comprehensive income	6,629	2,886
Total shareholders' equity	227,288	202,061
Total liabilities and shareholders' equity	\$ 588,778	\$ 561,215

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, 2009 AND 2008

(Unaudited, US Dollars, in thousands except share and per share data)	Three Months Ended		Nine Months Ended	
	2009	2008	2009	2008
Net sales	\$ 135,098	\$ 129,301	\$ 401,618	\$ 387,372
Cost of sales	31,985	47,998	101,700	117,284
Gross profit	103,113	81,303	299,918	270,088
Operating expenses				
Sales and marketing	55,012	50,210	162,547	153,652
General and administrative	20,819	19,293	64,694	60,252
Research and development	7,863	6,447	25,837	19,400
Amortization of intangible assets	1,668	5,347	4,944	15,220
Impairment of goodwill and certain intangible assets		289,523		289,523
Gain on sale of Pain Care® operations				(1,570)
	85,362	370,820	258,022	536,477
Operating income (loss)	17,751	(289,517)	41,896	(266,389)
Other income (expense), net				
Interest expense, net	(6,437)	(4,249)	(18,385)	(13,708)
Loss on refinancing of senior secured term loan		(5,735)		(5,735)
Unrealized non-cash gain (loss) on interest rate swap	(229)		1,046	
Other expense, net	(688)	(3,822)	(586)	(2,737)
	(7,354)	(13,806)	(17,925)	(22,180)
Income (loss) before income taxes	10,397	(303,323)	23,971	(288,569)
Income tax benefit (expense)	(4,209)	66,072	(8,960)	60,732
Net income (loss)	\$ 6,188	\$ (237,251)	\$ 15,011	\$ (227,837)
Net income (loss) per common share basic	\$ 0.36	\$ (13.87)	\$ 0.88	\$ (13.33)
Net income (loss) per common share diluted	\$ 0.36	\$ (13.87)	\$ 0.87	\$ (13.33)
Weighted average number of common shares basic	17,130,247	17,101,718	17,113,891	17,093,133
Weighted average number of common shares diluted	17,215,567	17,101,718	17,174,416	17,093,133

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, 2009 AND 2008

(Unaudited, US Dollars, in thousands)	2009	2008
Cash flows from operating activities:		
Net income (loss)	\$ 15,011	\$ (227,837)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	16,064	22,707
Amortization of debt costs	199	868
Provision for doubtful accounts	5,138	4,585
Provision for inventory obsolescence	6,769	13,708
Loss on refinancing of senior secured term loan		3,660
Impairment of goodwill and certain intangible assets		289,523
Impairment of investments held at cost		1,500
Deferred taxes	(2,015)	(76,861)
Share-based compensation	7,877	7,855
Minority interest	28	
Amortization of step up of fair value in inventory		365
Gain on sale of Pain Care® operations		(1,570)
Other	(159)	3,062
Change in operating assets and liabilities:		
Restricted cash	(2,141)	(352)
Accounts receivable	(18,357)	(13,805)
Inventories	(12,832)	(19,498)
Prepaid expenses and other current assets	(4,415)	(5,250)
Accounts payable	2,314	2,500
Current liabilities	14,743	(2,739)
Net cash provided by operating activities	28,224	2,421
Cash flows from investing activities:		
Capital expenditures	(16,073)	(15,831)
Proceeds from sale of investments held at cost	1,711	766
Proceeds from sale of Pain Care® operations		5,980
Net cash used in investing activities	(14,362)	(9,085)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	7	1,734
Repayments of long-term debt	(22,477)	(6,223)
Proceeds from (repayments of) bank borrowings, net	1,581	(2,377)
Payment of refinancing fees		(283)
Cash payment for purchase of minority interest in subsidiary	(1,143)	(501)
Tax benefit on non-qualified stock options	2	22
Net cash used in financing activities	(22,030)	(7,628)

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

Effect of exchange rate changes on cash	374	(486)
Net decrease in cash and cash equivalents	(7,794)	(14,778)
Cash and cash equivalents at the beginning of the year	14,594	25,064
Cash and cash equivalents at the end of the period	\$ 6,800	\$ 10,286

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

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

Orthofix International N.V. (the Company) is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical equipment, principally for the Orthopedics products market. The Company is comprised of four reportable segments: Domestic, Spinal Implants & Biologics, Breg and International. See Note 13 for a description of each segment.

NOTE 2: BASIS OF PRESENTATION

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures, normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States, have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. The balance sheet at December 31, 2008 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. For further information, refer to the Consolidated Financial Statements and Notes thereto of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

NOTE 3: RECENTLY ISSUED ACCOUNTING STANDARDS

In January 2009, the Company adopted the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 808 Collaborative Arrangements (ASC 808) (formerly known as Emerging Issues Task Force (EITF) 07-1 Accounting for Collaborative Arrangements). ASC 808 provides information related to the classification of the payments between participants, the appropriate income statement presentation, as well as disclosures related to certain collaborative arrangements. The adoption of ASC 808 did not have a material impact on the Company's results of operations or financial position, as the Company had applied this guidance since there was no prevailing authority previously.

In January 2009, the Company adopted ASC Subtopic 810-10 (ASC 810-10) (formerly known as Statement of Financial Accounting Standards (SFAS) No. 160, Non-controlling Interests in Consolidated Financial Statements, an Amendment of ARB 51). ASC 810-10 establishes accounting and reporting standards pertaining to ownership interest in subsidiaries held by parties other than the parent, the amount of net income attributable to the parent and to the non-controlling interest, changes in a parent's ownership interest, and the valuation of any retained non-controlling equity investment when a subsidiary is deconsolidated. ASC 810-10 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. ASC 810-10 and its adoption changed the method in which the Company accounted for a minority interest acquisition during the first quarter of 2009. It also requires the excess purchase price over the minority interest liability (at the time of the acquisition) to be recorded as a capital transaction. The disclosure requirements of ASC 810-10 did not have an impact on the Company's financial reporting as the remaining minority interest liability is immaterial.

In May 2009, the FASB issued ASC Topic 855 Subsequent Events (ASC 855) (formerly known as SFAS No. 165, Subsequent Events). ASC 855 provides authoritative accounting literature for a topic that was previously addressed only in auditing literature (AICPA AU Section 560, Subsequent Events). The guidance in ASC 855 is largely similar to the current guidance in the auditing literature with some exceptions that are not intended to result in significant changes in practice. Three modifications to the subsequent events guidance in AU Section 560 are: 1) to name the two types of subsequent events either as recognized subsequent events (currently referred to in practice as Type I subsequent events) or non-recognized subsequent events (currently referred to in practice as Type II subsequent events), 2) to modify the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued for public entities and 3) to require entities to disclose the date through which an entity has evaluated subsequent events and the basis for that date. ASC 855 is effective for

interim or annual financial periods ending after June 15, 2009. In accordance with the provisions of ASC 855, the Company has evaluated all subsequent events that occurred through November 6, 2009, the date the financial statements were issued. Refer to Note 20 for disclosures related to the Company's subsequent events.

Table of Contents**NOTE 4: SHARE-BASED COMPENSATION**

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

The following table shows the detail of share-based compensation by line item in the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2009 and 2008:

(US\$ in thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Cost of sales	\$ 166	\$	\$ 505	\$ 116
Sales and marketing	625	579	2,290	1,353
General and administrative	1,632	2,433	4,656	5,793
Research and development	138	186	426	593
Total	\$ 2,561	\$ 3,198	\$ 7,877	\$ 7,855

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

NOTE 5: RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform to the 2009 presentation. The reclassifications have no effect on previously reported net loss or shareholders' equity.

NOTE 6: INVENTORIES

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

Inventories were as follows:

(US\$ in thousands)	September	December 31,
	30, 2009	2008
Raw materials	\$ 9,847	\$ 9,314
Work-in-process	7,341	8,829
Finished products	64,224	57,151
Field inventory	16,198	13,633
Consignment inventory	27,529	23,426
	125,139	112,353
Less reserve for obsolescence	(24,123)	(21,168)
	\$ 101,016	\$ 91,185

Table of Contents**NOTE 7: GOODWILL**

The changes in the carrying value of goodwill by reportable segment for the period ended September 30, 2009 are as follows:

(US\$ in thousands)	Domestic	Spinal & Biologics	Breg	International	Total
At December 31, 2008	\$ 31,793	\$ 9,367	\$ 99,295	\$ 42,126	\$ 182,581
Foreign currency				2,627	2,627
At September 30, 2009	\$ 31,793	\$ 9,367	\$ 99,295	\$ 44,753	\$ 185,208

NOTE 8: PATENTS AND OTHER INTANGIBLE ASSETS

(US\$ in thousands)	September 30, 2009	December 31, 2008
Cost		
Patents and developed technologies	\$ 26,853	\$ 25,602
Trademarks definite lived (subject to amortization)	119	105
Trademarks indefinite lived (not subject to amortization)	23,502	23,382
Distribution networks	44,586	44,586
	95,060	93,675
Accumulated amortization		
Patents and developed technologies	(15,589)	(13,194)
Trademarks definite lived (subject to amortization)	(106)	(105)
Distribution networks	(30,061)	(26,830)
Patents and other intangible assets, net	\$ 49,304	\$ 53,546

Amortization expense for intangible assets is estimated to be approximately \$1.5 million for the remainder of 2009 and \$5.9 million, \$5.9 million, \$4.6 million, \$1.5 million and \$6.4 million for the periods ending December 31, 2010, 2011, 2012, 2013, and thereafter, respectively.

NOTE 9: BANK BORROWINGS

(US\$ in thousands)	September 30, 2009	December 31, 2008
Borrowings under line of credit	\$ 3,689	\$ 1,907

The weighted average interest rates on borrowings under lines of credit as of September 30, 2009 and December 31, 2008 were 4.93% and 5.86%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 4.8 million Euros (\$7.0 million) and 5.2 million Euros (\$7.3 million) at September 30, 2009 and December 31, 2008, respectively, in its Italian line of credit, which gives the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing. This line of credit is unsecured.

Table of Contents**NOTE 10: LONG-TERM DEBT**

(US\$ in thousands)	September 30, 2009	December 31, 2008
Long-term obligations	\$ 258,225	\$ 280,700
Other loans	160	162
	258,385	280,862
Less current portion	(3,336)	(3,329)
	\$ 255,049	\$ 277,533

On September 22, 2006 the Company's wholly-owned US holding company subsidiary, Orthofix Holdings, Inc. (Orthofix Holdings), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone Medical Inc. (Blackstone). Certain terms of the senior secured credit facility were amended September 29, 2008. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million and (2) a six-year revolving credit facility of \$45.0 million. As of September 30, 2009, the Company had no amounts outstanding under the revolving credit facility and \$258.2 million outstanding under the term loan facility. Obligations under the senior secured credit facility can have a floating interest rate of the London Inter-Bank Offered Rate (LIBOR) plus a margin, with a LIBOR floor of 3.0%, or prime rate plus a margin. As of September 30, 2009, the entire term loan obligation of \$258.2 million is at the prime rate plus a margin of 3.50%. The effective interest rates on the senior secured credit facility, including the impact of an interest rate swap (see Note 17), as of September 30, 2009 and December 31, 2008 were 9.0% and 8.4%, respectively.

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

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's senior secured credit facility. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of September 30, 2009 is \$130.8 million compared to \$111.3 million at December 31, 2008. In addition, the senior secured credit facility restricts the Company and subsidiaries that are not parties to the credit facility from access to cash held by Colgate Medical Limited and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of September 30, 2009 is \$13.2 million compared to \$11.0 million at December 31, 2008.

Weighted average interest rates on current maturities of long-term obligations as of September 30, 2009 and December 31, 2008 were 9.0% and 8.4%, respectively.

NOTE 11: COMMON SHARES

During the nine month period ended September 30, 2009, there were 27,656 shares of common stock issued upon the vesting of restricted stock and the exercise of outstanding stock options.

Table of Contents**NOTE 12: COMPREHENSIVE INCOME (LOSS)**

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and the effective portion of the gain (loss) for the Company's cross-currency swap which is designated and accounted for as a cash flow hedge (refer to Note 17). The components of and changes in accumulated other comprehensive income are as follows:

(US\$ in thousands)	Foreign Currency Translation Adjustments	Fair Value of Cross - Currency Swap	Accumulated Other Comprehensive Income/(Loss)
Balance at December 31, 2008	\$ (211)	\$ 3,097	\$ 2,886
Unrealized loss on cross-currency swap, net of tax of \$(943)		(2,426)	(2,426)
Foreign currency translation adjustment	6,169		6,169
Balance at September 30, 2009	\$ 5,958	\$ 671	\$ 6,629

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

(US\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income (loss)	\$ 6,188	\$ (237,251)	\$ 15,011	\$ (227,837)
Other comprehensive income (loss):				
Unrealized gain (loss) on derivative instrument(s), net of tax	159	(1,997)	(2,426)	(76)
Foreign currency translation adjustment	948	(5,953)	6,169	(5,782)
Total comprehensive income (loss)	\$ 7,295	\$ (245,201)	\$ 18,754	\$ (233,695)

NOTE 13: BUSINESS SEGMENT INFORMATION

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

Domestic

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

Spinal Implants & Biologics

Spinal Implants & Biologics (Spinal Implants & Biologics) consists of Blackstone and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Spinal Implants and Biologics specializes in the design, development and marketing of spinal implant and related human cellular and tissue based products (HCT/P products , often referred to as Biologic products). Spinal Implants & Biologics distributes its products through a network of domestic and international distributors, sales representatives and affiliates.

Table of Contents*Breg*

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

International

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

Group Activities

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

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

For the three month period ended September 30:

(US\$ in thousands)	External Sales		Intersegment Sales	
	2009	2008	2009	2008
Domestic	\$ 52,222	\$ 47,065	\$ 1,145	\$ 1,552
Spinal Implants & Biologics	28,017	25,338	291	349
Breg	23,724	22,377	1,138	1,392
International	31,135	34,521	7,214	6,240
Total	\$ 135,098	\$ 129,301	\$ 9,788	\$ 9,533

For the nine month period ended September 30:

(US\$ in thousands)	External Sales		Intersegment Sales	
	2009	2008	2009	2008
Domestic	\$ 155,654	\$ 138,397	\$ 4,853	\$ 4,856
Spinal Implants & Biologics	86,562	81,093	1,965	2,938
Breg	70,175	66,341	4,031	4,048
International	89,227	101,541	17,641	19,673
Total	\$ 401,618	\$ 387,372	\$ 28,490	\$ 31,515

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

Operating Income (Loss) (US\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Domestic	\$ 16,505	\$ 17,155	\$ 51,011	\$ 47,235
Spinal Implants & Biologics (1)(2)(3)	(2,430)	(309,201)	(16,898)	(319,993)
Breg	3,210	2,206	9,227	9,273
International	5,066	4,741	12,516	14,451
Group Activities	(4,350)	(4,309)	(14,507)	(16,525)
Eliminations	(250)	(109)	547	(830)
Total	\$ 17,751	\$ (289,517)	\$ 41,896	\$ (266,389)

- (1) Includes \$0.8 million of research and development expense from collaborative arrangements and \$0.6 million of restructuring charges for the three months ended September 30, 2009.
- (2) Includes \$5.7 million of research and development expense from collaborative arrangements and \$3.6 million of restructuring charges for the nine months ended September 30, 2009.
- (3) Includes impairment charges on goodwill and certain intangible assets of \$289.5 million during the three and nine months ended September 30, 2008.

Table of Contents

The following tables present sales by market sector for the three months ended September 30, 2009 and 2008:

**Sales by Market Sector
for the three month period ended September 30, 2009**

(US\$ in thousands)	Domestic	Spinal Implants & Biologics	Breg	International	Total
Spine	\$ 39,609	\$ 28,017	\$	\$ 510	\$ 68,136
Orthopedics	12,613			20,637	33,250
Sports Medicine			23,724	940	24,664
Vascular				3,904	3,904
Other				5,144	5,144
Total	\$ 52,222	\$ 28,017	\$ 23,724	\$ 31,135	\$ 135,098

**Sales by Market Sector
for the three month period ended September 30, 2008**

(US\$ in thousands)	Domestic	Spinal Implants & Biologics	Breg	International	Total
Spine	\$ 35,340	\$ 25,338	\$	\$ 640	\$ 61,318
Orthopedics	11,725			22,099	33,824
Sports Medicine			22,377	1,323	23,700
Vascular				4,274	4,274
Other				6,185	6,185
Total	\$ 47,065	\$ 25,338	\$ 22,377	\$ 34,521	\$ 129,301

Table of Contents

The following tables present sales by market sector for the nine months ended September 30, 2009 and 2008:

**Sales by Market Sector
for the nine month period ended September 30, 2009**

(US\$ in thousands)	Domestic	Spinal Implants & Biologics	Breg	International	Total
Spine	\$ 117,034	\$ 86,562	\$	\$ 1,399	\$ 204,995
Orthopedics	38,620			56,848	95,468
Sports Medicine			70,175	3,194	73,369
Vascular				12,574	12,574
Other				15,212	15,212
Total	\$ 155,654	\$ 86,562	\$ 70,175	\$ 89,227	\$ 401,618

**Sales by Market Sector
for the nine month period ended September 30, 2008**

(US\$ in thousands)	Domestic	Spinal Implants & Biologics	Breg	International	Total
Spine	\$ 104,143	\$ 81,093	\$	\$ 1,252	\$ 186,488
Orthopedics	34,254			62,665	96,919
Sports Medicine			66,341	3,871	70,212
Vascular				13,391	13,391
Other				20,362	20,362
Total	\$ 138,397	\$ 81,093	\$ 66,341	\$ 101,541	\$ 387,372

NOTE 14: RESTRUCTURING CHARGES

In the fourth quarter of 2008, as part of the Company's strategic plan to strengthen the business, the Company initiated a restructuring plan to improve operations and reduce costs at Blackstone. The plan involves the consolidation of substantially all of Blackstone's current operations in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and US orthopedics business in the Dallas, TX area. The Company plans to complete the restructuring and consolidation by the second quarter of 2010, at which time the Company anticipates a total restructuring expense of \$3.6 million. During the three and nine months ended September 30, 2009, the Company recorded net restructuring charges of \$0.6 million and \$3.6 million, respectively, which were primarily related to severance costs and accelerated depreciation costs related to shortening lives of assets which will be disposed. These restructuring costs are recorded in general and administrative expense and are classified in the Spinal Implants & Biologics segment.

Table of Contents

The following table presents changes in the restructuring liability, which is included within Other Current Liabilities in the Company's condensed consolidated balance sheets as of September 30, 2009 and December 31, 2008:

(US\$ in thousands)	Severance	Assets Abandoned	Total
Balance at December 31, 2008	\$ 548	\$	\$ 548
Charges	2,565	1,020	3,585
Cash Payments	(1,018)		(1,018)
Non-cash Items		(1,020)	(1,020)
Balance at September 30, 2009	\$ 2,095	\$	\$ 2,095

NOTE 15: INCOME TAXES

The reported year to date tax provision as a percentage of income before income taxes was 37.4%. The principal factors affecting the Company's tax rate are the Company's mix of earnings among various tax jurisdictions and a benefit related to a restructuring of the Company's European operations in 2006 to optimize the Company's supply chain. This benefit, which results in ongoing tax efficiencies is partially offset by current period losses in certain foreign jurisdictions for which the Company does not currently provide a tax benefit.

As of September 30, 2009, the Company's gross unrecognized tax benefit was \$1.2 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, 2009, the Company had approximately \$0.4 million accrued for interest and penalties. The entire \$1.6 million of unrecognized tax benefit would affect the Company's effective tax rate if recognized. It is possible that the amount of unrecognized tax benefits may decrease by \$0.5 million over the next twelve months due to the potential settlement of tax examinations.

The Company is subject to tax examinations in all major taxing jurisdictions in which it operates. The Company files a consolidated income tax return in the US federal jurisdiction and numerous consolidated and separate income tax returns in many state and foreign jurisdictions. The statute of limitations with respect to US federal tax filings is closed for years prior to December 31, 2004. The statute of limitations for the various US state tax filings is closed in most instances for years prior to December 31, 2006. The Company is currently under examination by the Internal Revenue Service (IRS) for the tax years ended December 31, 2005 and December 31, 2006. All issues raised to date by the IRS are reflected in the current unrecognized tax benefits. There are certain US state tax statutes open for years from 1997 forward due to current examinations. The statutes of limitations with respect to the major foreign tax filing jurisdictions are generally closed for years prior to December 31, 2004.

NOTE 16: EARNINGS PER SHARE

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Weighted average common shares-basic	17,130,247	17,101,718	17,113,891	17,093,133
Effect of dilutive securities	85,320		60,525	
Weighted average common shares-diluted	17,215,567	17,101,718	17,174,416	17,093,133

Table of Contents

For the three and nine months ended September 30, 2009, the Company did not include 2,953,381 and 3,252,174 options, respectively, in the diluted shares outstanding calculation because their inclusion would have been anti-dilutive or because their exercise price exceeded the average market price of the Company's common stock during the period.

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

NOTE 17: DERIVATIVE INSTRUMENTS

In 2006, the Company entered into a cross-currency swap agreement to manage its foreign currency exposure related to a portion of the Company's intercompany receivable of a US dollar functional currency subsidiary that is denominated in Euro. The derivative instrument, a ten-year fully amortizable agreement with a notional amount of \$63.0 million, is scheduled to expire on December 30, 2016. The instrument is designated as a cash flow hedge. The amount outstanding under the agreement as of September 30, 2009 and December 31, 2008 is \$56.7 million. Under the agreement, the Company pays Euro and receives US dollars based on scheduled cash flows in the agreement. The Company recognized an unrealized gain (loss) on the change in fair value of this swap arrangement of \$0.2 million and \$(2.4) million, net of tax, within other comprehensive income in the three and nine months ended September 30, 2009, respectively. The Company recognized an unrealized gain (loss) on the change in fair value of this swap arrangement of \$(1.0) million and \$0.2 million, net of tax, within other comprehensive loss in the three and nine months ended September 30, 2008, respectively.

In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the second and third quarters of 2008, the interest rate Swap was accounted for as a cash flow hedge, and changes in its value were recorded as part of accumulated other comprehensive income on the balance sheet. Due to declining interest rates and a LIBOR floor in the Company's amended credit facility, the Swap was no longer deemed highly effective. Therefore, during the fourth quarter of 2008, the Company recognized in earnings an unrealized, non-cash loss of approximately \$8.0 million which resulted from changes in the fair value of the Company's interest rate Swap. Cash flow accounting is no longer applied and mark-to-market adjustments are required to be reported in current earnings through the expiration of the Swap in June 2011. For the three and nine months ended September 30, 2009, the Company recorded an unrealized gain (loss) of \$(0.2) million and \$1.0 million, respectively, in other income (expense), net on the statement of operations. The Company recognized an unrealized loss on the change in fair value of this swap arrangement of \$(1.0) million and \$(0.3) million, net of tax, for the three and nine months ended September 30, 2008, respectively, within other comprehensive loss. The Swap continues to provide an economic hedge against fluctuating interest rate exposure on the \$150.0 million portion of outstanding debt it covers, should the LIBOR interest rate rise above 3.73%. As required by ASC Topic 815 - Derivatives and Hedging (ASC 815) (formerly known as SFAS No. 161 - Disclosures about Derivative Instruments and Hedging Activities), 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 income (loss).

(US\$ in thousands)	Fair value:		Balance sheet location	Amount of gain (loss) recognized in OCI
	favorable (unfavorable)			
As of September 30, 2009				
Cross-currency swap	\$ (5,879)		Other long-term liabilities	\$ (2,426)
Interest rate swap	\$ (6,929)		Other current liabilities	\$
As of September 30, 2008				
Cross-currency swap	\$ (1,751)		Other long-term liabilities	\$ 200
Interest rate swap	\$ (424)		Other current liabilities	\$ (276)

(US\$ in thousands)	For the three months ended		For the nine months ended	
Amount of gain (loss)	September 30,		September 30,	
recognized in income (loss)	2009	2008	2009	2008
Interest rate swap	\$ (229)	\$	\$ 1,046	\$

Table of Contents**NOTE 18: FAIR VALUE MEASUREMENTS**

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

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

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

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

As of September 30, 2009, the Company held certain items that are required to be measured at fair value on a recurring basis. These included cash equivalents, restricted cash, accounts receivable, short-term bank borrowings, accounts payable, long-term secured debt, an interest rate derivative contract, and a cross currency derivative contract. Cash equivalents consist of short-term, highly liquid, income-producing investments, all of which have original maturities of 90 days or less, including money market funds. Restricted cash, accounts receivable, short-term bank borrowings and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company's long-term secured debt carries a floating rate of interest and therefore, the carrying value is considered to approximate the fair value. The derivative instruments are related to the Company's interest rate and foreign currency hedges.

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

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

(US\$ in thousands)	Balance September 30, 2009	Level 1	Level 2	Level 3
Derivative Financial Instruments ⁽¹⁾				
Cash Flow Hedges				
Interest rate hedge	\$ (6,929)	\$	\$ (6,929)	\$
Cross currency hedge	\$ (5,879)	\$	\$ (5,879)	\$

⁽¹⁾ See Note 17,
Derivative
Instruments .

Table of Contents**NOTE 19: CONTINGENCIES***Litigation*

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

On or about January 7, 2008, the Company received a federal grand jury subpoena from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On or about April 29, 2009, counsel for the Company received a HIPAA subpoena issued by the US 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 June 15, 2009, Orthofix, Inc., and Blackstone, executed an agreement with the United States Attorney's Office for the District of Massachusetts (the Tolling Agreement) extending an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate. The Tolling Agreement extended the period tolling the statute of limitations to include the period from December 1, 2008 through and including December 31, 2009.

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 US 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 US Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. On November 21, 2008, the US Department of Justice filed a notice of non-intervention in the case. The complaint was served on Blackstone on or about March 24, 2009. Counsel for the plaintiffs filed an amended complaint on June 4, 2009. The amended complaint sets forth a cause of action against Blackstone under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants; Orthofix is not named as a defendant in the amended complaint. The Company believes that this lawsuit is related to the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and the United States Attorney's Office for the District of Massachusetts. The Company intends to defend vigorously against this lawsuit. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of the US Department of Justice and prior to the unsealing of the complaint (which was unsealed by the court on or about November 24, 2008), the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter.

Table of Contents

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

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

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have agreed to indemnify the Company for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders are limited to a cumulative aggregate amount of \$66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was \$50.0 million. As of September 30, 2009, the escrow fund, which has subsequently accrued interest, contained \$54.0 million. The Company is also entitled to seek direct personal recourse against certain principal shareholders of Blackstone after all monies on deposit in the escrow fund have been paid out or released or are the subject of pending or unresolved indemnification claims but only for a period of six years from the closing date of the Merger and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

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

The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund and there can be no assurance that losses to the Company from these matters will not exceed the amount of the escrow fund. Expenses incurred by the Company relating to the above matters are recorded as an escrow receivable in the Company's financial statements to the extent the Company believes, among other things, that collection of the claims is reasonably assured. Expenditures related to such matters for which the Company believes collection is doubtful are recognized in earnings when incurred. As of September 30, 2009 and December 31, 2008, included in Prepaid Expenses and Other Current Assets is approximately \$13.3 million and \$8.3 million, respectively, of escrow

receivable balances related to the Blackstone matters described above. These amounts include, among other things, attorneys' fees and costs related to the government investigations manifested by the subpoenas described above, the stock option-related claims described above, and costs related to the qui-tam action described above. As described above, some of these reimbursement claims are being contested by the representative of the former shareholders of Blackstone. To mitigate the risk that some reimbursement claims will not be collected, the Company records a reserve against the escrow receivable during the period in which reimbursement claims are recognized.

Table of Contents

On or about April 10, 2009, the Company received a HIPAA subpoena (HIPAA subpoena) issued by the US Attorney s Office for the District of Massachusetts. The subpoena seeks documents for the period January 1, 1995 through the date of the subpoena. The Company believes that the subpoena concerns the classification and marketing of its bone growth stimulators and related matters. On or about September 21, 2009, the Company received an additional HIPAA subpoena issued by the U.S. Attorney s Office for the District Of Massachusetts in connection with this investigation. The subpoena seeks additional documents pertaining to the investigation for the period January 1, 1995 through the date of the subpoena. The Company intends to cooperate with the government s requests. The Company is unable to predict what actions, if any, might be taken by the government or what impact, if any, the outcome of this matter might have on the Company s consolidated financial position, results of operations or cash flows.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the US District Court for the District of Massachusetts against Orthofix, Inc., the Company, and other companies that have allegedly manufactured bone growth stimulation devices, including Orthologic Corp., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. By order entered on March 24, 2009, the court unsealed the case. The amended 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 amended complaint also includes claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-kickback Act by providing free products to physicians, waiving patients insurance co-payments, and providing inducements to independent sales agents to generate business. The Company believes that this lawsuit is related to the matter described above involving the HIPAA subpoena. The Company and Orthofix, Inc. were served on or about September 8, 2009, and intend to defend vigorously against this lawsuit.

On or about July 2, 2009, the Company obtained a copy of a qui tam complaint filed by Marcus Laughlin that is pending in the US District Court for the District of Massachusetts against the Company. This complaint has been consolidated with the complaint described in the immediately preceding paragraph, and was unsealed on June 30, 2009. The complaint alleges violations of the False Claims Act, fraudulent billing, illegal kickbacks and wrongful termination based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products, provided physicians kickbacks in the form of free units, referral fees, and fitting fees, and that the defendant and its competitors discussed together strategies to encourage higher government pricing for the products. The complaint also alleges that TRICARE has been reimbursing the Company for its Cervical Stim® product without approval to do so. An amended complaint alleges conspiracy and violations of the Sherman Anti-Trust Act in connection with the same alleged conduct. The Company was served with the complaint on or about September 9, 2009 and intends to defend vigorously against this lawsuit.

Table of Contents

Effective October 29, 2007, Blackstone entered into a settlement agreement of a patent infringement lawsuit brought by certain affiliates of Medtronic Sofamor Danek USA Inc. In that lawsuit, the Medtronic plaintiffs had alleged that they were the exclusive licensees of certain US patents and that Blackstone's making, selling, offering for sale, and using its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate 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 Company's consolidated financial position, results of operations or cash flows. On July 20, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. The Company was subsequently notified by legal counsel of the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

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

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

NOTE 20: SUBSEQUENT EVENT

As further described in Note 19, as of September 30, 2009 and December 31, 2008, included in Prepaid Expenses and Other Current Assets is approximately \$13.3 million and \$8.3 million, respectively, of escrow receivable balances related to the Blackstone matters described above. During October 2009, the Company received approximately \$1.0 million of proceeds from the escrow fund that was established as part of the Blackstone acquisition. These proceeds represent a portion of the escrow claims that had been previously submitted by the Company.

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

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

The following discussion and analysis addresses our liquidity, financial condition, and the results of our operations for the three and nine months ended September 30, 2009 compared to our results of operations for the three and nine months ended September 30, 2008. These discussions should be read in conjunction with our historical consolidated financial statements and related notes thereto and the other financial information included in this Form 10-Q and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

General Overview

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

We believe the keys to reaching our publicly stated financial goals for 2009 are primarily related to improvements in the operating performance of the Spinal Implants & Biologics segment, including:

- An acceleration in the growth of revenue,
- An increase of the gross profit margin, and
- A reduction in operating expenses as a percentage of net sales

We expect the acceleration of revenue growth will be driven by the introduction of a number of key new products in 2009, including the Trinity[®] Evolution allograft, the Firebird pedicle screw system, the PILLAR SA interbody device, and the Ascent LE posterior cervical spine system. As of September 30, 2009, each of these new products had been introduced to the market and was contributing to the year-over-year net sales growth reported by the Company.

Our gross profit margin is expected to increase as a result of the introduction of the key new products indicated above, primarily Trinity[®] Evolution . We recognize a 100% gross profit margin from the marketing fees earned from the sales of this allograft, compared to approximately 50% gross profit margin on our previous Trinity[®] product. This is due to the fact that we are not required to purchase inventory of Trinity[®] Evolution , whereas, previously, we were required to purchase inventory of the old Trinity[®] product and record the associated cost of sales.

Our operating expenses are expected to decrease as a percentage of net sales as we leverage our operating infrastructure against the expected increase in net sales noted above. Additionally, we initiated a reorganization and consolidation plan, during the fourth quarter of 2008, to reduce operating expenses by eliminating redundancies and increasing operating efficiency. This plan includes the consolidation of operations in our Springfield, MA and Wayne, NJ locations into the Company's operations in the Dallas, TX area. For a further discussion about this reorganization and consolidation plan, please refer to the explanation provided in our General and Administrative Expense section of this Management Discussion and Analysis.

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

Table of Contents

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

Our reporting currency is the United States Dollar. All balance sheet accounts, except shareholders' equity, are translated at period-end exchange rates, and revenue and expense items are translated at weighted average rates of exchange prevailing during the period. Gains and losses resulting from foreign currency transactions are included in other income (expense), net on the statements of operations. Gains and losses resulting from the translation of foreign currency net assets are recorded in the accumulated other comprehensive income component of shareholders' equity.

Our financial condition, results of operations and cash flows are not significantly impacted by seasonality trends. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. Certain of the Breg bracing products experience greater demand in the fall and winter corresponding with high school and college football schedules and winter sports. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar income and expenditures. During the nine months ended September 30, 2009 and all of 2008, we have used a derivative instrument to hedge certain foreign currency fluctuation exposures. During the nine months ended September 30, 2009 and the second half of 2008, we have used a derivative instrument to hedge certain interest rate exposure on LIBOR-based borrowings. See Item 3 Quantitative and Qualitative Disclosures About Market Risk.

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

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

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

Business Segment:

(US\$ in thousands)	Three Months Ended September 30,				
	2009		2008		Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	
Domestic	\$ 52,222	39%	\$ 47,065	36%	
Spinal Implants & Biologics	28,017	21%	25,338	20%	11%
Breg	23,724	17%	22,377	17%	6%
International	31,135	23%	34,521	27%	-10%
Total	\$ 135,098	100%	\$ 129,301	100%	4%

(US\$ in thousands)	Nine Months Ended September 30,				
	2009		2008		Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	
Domestic	\$ 155,654	39%	\$ 138,397	36%	
Spinal Implants & Biologics	86,562	22%	81,093	21%	7%
Breg	70,175	17%	66,341	17%	6%
International	89,227	22%	101,541	26%	-12%
Total	\$ 401,618	100%	\$ 387,372	100%	4%

Table of Contents**Market Sector:**

(US\$ in thousands)	Three Months Ended September 30,					
	2009		2008		Reported Growth	Constant Currency Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales		
Spine	\$ 68,136	50%	\$ 61,318	48%	11%	11%
Orthopedics	33,250	25%	33,824	26%	-2%	6%
Sports Medicine	24,664	18%	23,700	18%	4%	5%
Vascular	3,904	3%	4,274	3%	-9%	-5%
Other	5,144	4%	6,185	5%	-17%	-5%
Total	\$ 135,098	100%	\$ 129,301	100%	4%	7%

(US\$ in thousands)	Nine Months Ended September 30,					
	2009		2008		Reported Growth	Constant Currency Growth
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales		
Spine	\$ 204,995	51%	\$ 186,488	48%	10%	10%
Orthopedics	95,468	24%	96,919	25%	-1%	8%
Sports Medicine	73,369	18%	70,212	18%	4%	5%
Vascular	12,574	3%	13,391	4%	-6%	-1%
Other	15,212	4%	20,362	5%	-25%	-9%
Total	\$ 401,618	100%	\$ 387,372	100%	4%	7%

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009 (%)	2008 (%)	2009 (%)	2008 (%)
Net sales	100	100	100	100
Cost of sales	24	37	25	30
Gross profit (1)	76	63	75	70
Operating expenses:				
Sales and marketing	41	39	41	40
General and administrative	15	15	16	15
Research and development	6	5	7	5
Amortization of intangible assets	1	4	1	4
Gain on sale of Pain Care® operations				
Impairment of goodwill and intangible assets		224		75
Total operating income (loss)	13	(224)	10	(69)
Net income (loss)	5	(184)	4	(59)

(1) Includes effect of obsolescence provision representing approximately 9% and 3% points, respectively, for the three and nine months ended September 30, 2008.

Three Months Ended September 30, 2009 Compared to Three Months Ended September 30, 2008

Net sales increased 4% to \$135.1 million in the third quarter of 2009 compared to \$129.3 million for the same period last year. The impact of foreign currency decreased sales by \$3.6 million during the third quarter of 2009 when compared to the third quarter of 2008.

Sales by Business Segment:

Net sales in Domestic increased to \$52.2 million in the third quarter of 2009 compared to \$47.1 million for the same period last year, an increase of 11%. Domestic's net sales represented 39% and 36% of total net sales during the third quarter of 2009 and 2008, respectively. The increase in Domestic's net sales was partially the result of a 12% increase in sales in our Spine market sector, which was mainly driven by increased sales of our Spinal-Stim® and Cervical-Stim® products. The increase in Domestic's net sales was also attributable to an 8% increase in our Orthopedics market sector which included a 14% increase in sales of Physio-Stim® products and a 16% increase in sales of our external fixation products as compared to the same period in the prior year. Partially offsetting these sales increases was a decrease of 29% in the sales of our biologics products as a result of our replacement of the Trinity® product line with Trinity® Evolution. Although biologics sales decreased, the quantity of product sold increased in the third quarter of 2009 compared to the third quarter of 2008 because, under the terms of the agreement, we recognized marketing fees of 70% of the end-user sales price of Trinity® Evolution compared to 100% of the end-user sales price

of Trinity[®]. During the three months ended September 30, 2009, Domestic generated \$0.6 million in revenues of Trinity[®] Evolution .

Domestic Sales by Market Sector:

(US\$ in thousands)	Net Sales for the Three Months Ended September 30,			Growth
	2009	2008		
Spine	\$ 39,609	\$ 35,340		12%
Orthopedics	12,613	11,725		8%
Total	\$ 52,222	\$ 47,065		11%

Table of Contents

Net sales in Spinal Implants & Biologics increased \$2.7 million to \$28.0 million in the third quarter of 2009 compared to \$25.3 million for the same period last year, an increase of 11%. Spinal Implants & Biologics net sales represented 21% and 20% of total net sales during the third quarter of 2009 and 2008, respectively. The increase in sales was primarily related to a 21% increase in our thoracolumbar product sales due to the introduction of the new Firebird pedicle screw system during the second quarter of 2009. Sales of our interbody and cervical products increased by 22% and 10%, respectively, when compared to the same period in the prior year. These sales increases were partially offset by a 19% sales decrease in our biologics products when compared to the same period last year as a result of our replacement of the Trinity[®] product line with Trinity[®] Evolution. Although biologics sales decreased, the quantity of product sold increased in the third quarter of 2009 compared to the third quarter of 2008 because, under the terms of the agreement, we recognized marketing fees of 70% of the end-user sales price of Trinity[®] Evolution compared to 100% of the end-user sales price of Trinity[®]. Full market release of our new Trinity[®] Evolution stem cell-based allograft occurred on July 1, 2009 with sales reaching \$3.5 million during the third quarter of 2009. All of Spinal Implants & Biologics sales are recorded in our Spine market sector.

Net sales in Breg increased \$1.3 million to \$23.7 million in the third quarter of 2009 compared to \$22.4 million for the same period last year, an increase of 6%. Breg's net sales represented 17% of total net sales during both third quarters of 2009 and 2008. The increase in Breg's net sales was primarily due to a 9% increase in sales of our Breg bracing products when compared to the same period in the prior year, primarily as a result of the sales of our new products which include spine bracing. Further, sales of our cold therapy products increased 6% over the same period in the prior year which is due to the recent introduction of our Kodiak[®] cold therapy products. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International decreased 10% to \$31.1 million in the third quarter of 2009 compared to \$34.5 million for the same period last year. International's net sales represented 23% and 27% of our total net sales in the third quarter of 2009 and 2008, respectively. The impact of foreign currency decreased International net sales by 10% or \$3.5 million, during the third quarter of 2009 as compared to the third quarter of 2008. On a constant currency basis, sales for the Orthopedics sector increased 5% in the third quarter of 2009 when compared to the prior year. Within the Orthopedics sector, external fixation, stimulation, and deformity correction increased 4%, 18%, and 72% respectively, on a constant currency basis, when compared with the same period last year. Sales of our Vascular and Other distributed products both decreased 5% on a constant currency basis when compared to the same period in the prior year.

International Sales by Market Sector:

(US\$ in thousands)	Net Sales for the Three Months Ended September 30,		Reported Growth	Constant Currency Growth
	2009	2008		
Spine	\$ 510	\$ 640	-20%	-20%
Orthopedics	20,637	22,099	-7%	5%
Sports Medicine	940	1,323	-29%	-21%
Vascular	3,904	4,274	-9%	-5%
Other	5,144	6,185	-17%	-5%
Total	\$ 31,135	\$ 34,521	-10%	0%

Table of Contents*Sales by Market Sector:*

Sales of our Spine products increased to \$68.1 million in the third quarter of 2009 compared to \$61.3 million in the third quarter of 2008. Sales of our Cervical-Stim[®] and Spinal-Stim[®] products increased 7% and 17%, respectively, in the third quarter of 2009 compared to 2008. In addition, sales of our Spinal Implants & Biologics products increased 10% over the same period in the prior year due to the introduction of new thoracolumbar products previously discussed as well as increased sales of our interbody and cervical products. Also, the full market release of our new Trinity[®] Evolution stem cell-based allograft occurred on July 1, 2009 replacing the former Trinity[®] product line. Sales of Trinity[®] Evolution reached \$3.5 million during the third quarter of 2009. Under the terms of the agreement, we recognized marketing fees of 70% of the end-user sales price of Trinity[®] Evolution compared to 100% of the end-user sales price of Trinity[®]. Spine product sales were 50% and 48% of our total net sales in the third quarters of both 2009 and 2008, respectively.

Sales of our Orthopedics products decreased \$0.6 million to \$33.3 million in the third quarter of 2009 compared to \$33.8 million for the same period last year. On a constant currency basis, sales increased 6% compared to the same period last year due to increased sales of our Physio Stim[®], external fixation, and deformity correction products. Orthopedic product sales were 25% of our total net sales in the third quarter of 2009 compared to 26% for the same period last year.

Sales of our Sports Medicine products increased 4% to \$24.7 million in the third quarter of 2009 compared to \$23.7 million for the same period last year. As discussed above, the increase of \$1.0 million is primarily due to sales of our Breg bracing and cold therapy products. Sports Medicine product sales were 18% of our total net sales in both the third quarters of 2009 and 2008.

Sales of our Vascular products, which consist of our A-V Impulse System[®], decreased 9% to \$3.9 million in the third quarter of 2009 compared to \$4.3 million for the same period last year. On a constant currency basis, sales decreased 5% compared to the prior period. Vascular product sales were 3% of our total net sales in both the third quarters of 2009 and 2008.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our Woman's Care line, decreased 17% to \$5.1 million in the third quarter of 2009 when compared to \$6.2 million for the same period last year. On a constant currency basis, sales decreased 5% when compared to the third quarter of 2008. We distribute the Laryngeal Mask product in the United Kingdom and in Italy. We will transition out of the agreements to distribute the Laryngeal Mask product in Italy and in the United Kingdom, in October 2009 and June 2010, respectively. Other product sales were 4% and 5% of our total net sales in both the third quarters of 2009 and 2008, respectively.

Gross Profit Our gross profit increased 27% to \$103.1 million in the third quarter of 2009, compared to \$81.3 million for the same period last year. Gross profit as a percent of net sales in the third quarter of 2009 was 76.3% compared to 62.9% for the same period last year. In the quarter ended September 30, 2008, due to reduced projections in revenue, distributor terminations, new products, and the replacement of one of our products with a successor product, the Company changed its estimates regarding the inventory allowance at Blackstone, primarily based on estimated net realizable value using assumptions about future demand and market conditions. The change in estimate resulted in an increase in the reserve for obsolescence of approximately \$10.9 million. In addition, the Company recorded approximately \$0.6 million of expense related to Blackstone instrumentation equipment, also as a result of the replacement of one of our products with a successor product. Gross profit as a percent of net sales in the third quarter of 2008 was 62.9%. Gross profit, excluding the additional reserve recorded at Blackstone was 71.8% in the quarter ended September 30, 2008. Excluding the negative impacts in the prior year, the increase in the gross profit is primarily due to the increased sales of higher margin stimulation products and Spinal Implants & Biologics products.

Sales and Marketing Expense Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expense increased \$4.8 million, or 10%, to \$55.0 million in the third quarter of 2009 compared to \$50.2 million in the third quarter of 2008. As a percent of net sales, sales and marketing expense was 40.7% and 38.8% in the third quarter of 2009 and 2008, respectively. This increase is primarily the result of an increase in commission expenses reflecting the implementation of sales programs with new distributor programs. This increased investment in sales and marketing has facilitated the development of new customer relationships and increased sales in both the spine stimulation and

orthopedic businesses.

Table of Contents

General and Administrative Expense General and administrative expense increased \$1.5 million, or 8%, in the third quarter of 2009 to \$20.8 million compared to \$19.3 million in the third quarter of 2008. The increase is primarily due to a restructuring charge to consolidate substantially all of Blackstone's current operations in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and US orthopedics business in the Dallas, TX area. In addition, general and administrative expenses were also higher compared with the prior year due to infrastructure increases in some faster growing international markets. General and administrative expense as a percent of net sales was 15.4% in the third quarter of 2009 compared to 14.9% for the same period last year.

Research and Development Expense Research and development expense increased \$1.4 million in the third quarter of 2009 to \$7.9 million compared to \$6.4 million for the same period last year. This increase is primarily the result of our collaborative arrangement with Intelligent Implant Systems (IIS) for which we made an \$0.8 million milestone payment during the third quarter of 2009. As a percent of sales, research and development expense was 5.8% in the third quarter of 2009 compared to 5.0% for the same period last year. We do not expect to incur any further expense in 2009 related to the IIS agreement; see Liquidity and Capital Resources for further detail.

Amortization of Intangible Assets Amortization of intangible assets decreased \$3.7 million in the third quarter of 2009 to \$1.7 million compared to \$5.3 million for the same period last year. This decrease is primarily attributed to the impairment of \$105.7 million of definite-lived intangible assets at Blackstone during the third quarter of 2008.

Impairment of Goodwill and Certain Intangible Assets In the third quarter of 2008, we incurred \$289.5 million of expense related to the impairment of goodwill and certain intangible assets. As part of our debt refinancing completed in September 2008, five year projections were prepared for Blackstone. These projections provided an indication of impairment. Accordingly, an interim impairment test was performed in accordance with ASC Topic 350 Intangibles Goodwill and Other (formerly known as SFAS No. 142, Goodwill and Other Intangible Assets,). Based on this interim test, we determined that the Blackstone trademark, an indefinite-lived intangible asset, was impaired by \$57.0 million. In addition, we determined that the carrying amount of goodwill related to Blackstone exceeded its implied fair value, and recognized a goodwill impairment loss of \$126.9 million.

In accordance with ASC Topic 360 Property, Plant and Equipment (formerly known as SFAS No. 144 Accounting for the Impairment or Disposal of Long-Lived Assets), we determined that a triggering event had occurred with respect to the definite-lived intangible assets at Blackstone. We compared the expected cash flows to be generated by the definite lived intangible on an undiscounted basis to the carrying value of the intangible asset. We determined the carrying value exceeded the undiscounted cash flow and impaired the distribution network and technologies at Blackstone to the fair value which resulted in an impairment charge of \$105.7 million.

Interest Expense, net Interest expense, net was \$6.4 million for the third quarter of 2009 compared to \$4.2 million for the same period last year. Although our overall senior secured term loan balance has decreased when compared to the same period in the prior year, our effective interest rate has increased which is generating the additional interest expense. Included in interest expense, net for the third quarter of 2009 and 2008 was interest expense of \$6.0 million and \$3.3 million, respectively, related to the senior secured term loan used to finance the Blackstone acquisition.

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

Table of Contents

Unrealized Non-cash Loss on Interest Rate Swap In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the fourth quarter of 2008, the Company recognized in earnings an unrealized, non-cash loss of approximately \$(8.0) million when it was determined that the Swap was no longer deemed highly effective. Therefore, cash flow accounting is no longer applied and mark-to-market adjustments are required to be reported in current earnings through the expiration of the swap in June 2011. For the three months ended September 30, 2009, the Company recorded an unrealized non-cash loss of \$(0.2) million in other income (expense), net.

Other Income (Expense), net Other income (expense), net reflected an expense of \$(0.7) million for the third quarter of 2009 compared to an expense of \$(3.8) million for the same period last year, an improvement of \$3.1 million. The improvement can be mainly attributed to the effect of foreign exchange. During the third quarter of 2008, notably in September, we recorded foreign exchange losses of \$2.2 million principally as a result of a rapid strengthening of the US Dollar against various foreign currencies, including the Euro, Pound, Peso and Brazilian Real. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the US Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies.

Income Tax (Benefit) Expense Our effective tax rate was an expense of 40.5% and a benefit of 21.8% during the third quarters of 2009 and 2008, respectively. The effective tax rate for the third quarter of 2009 included an unfavorable discrete item resulting from additions to reserves for unrecognized tax benefits. The effective tax rate benefit for the third quarter of 2008 included unfavorable discrete items resulting from the impairment of goodwill for which we received no tax benefit. Excluding these discrete items in the third quarters of 2009 and 2008, our effective tax rate was an expense of 35.9% and a benefit of (38.8%), respectively. The decrease in the effective tax rate excluding discrete items is primarily attributable to changes in the jurisdictional mix of earnings.

Net Income (Loss) Net income for the third quarter of 2009 was \$6.2 million, or \$0.36 per basic and diluted share, compared to a net loss of \$(237.3) million, or \$(13.87) per basic and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,130,247 and 17,101,718 during the third quarters of 2009 and 2008, respectively. The weighted average number of diluted common shares outstanding was 17,215,567 and 17,101,718 during the third quarters of 2009 and 2008, respectively.

Nine Months Ended September 30, 2009 Compared to Nine Months Ended September 30, 2008

Net sales increased 4% to \$401.6 million for the nine months of 2009 compared to \$387.4 million for the same period last year. The impact of foreign currency decreased net sales by \$14.0 million during the nine months of 2009 when compared to the same period last year.

Sales by Business Segment:

Net sales in Domestic increased to \$155.7 million for the nine months ended September 30, 2009 compared to \$138.4 million for the same period last year, an increase of 12%. Domestic's net sales represented 39% and 36% of total net sales for the nine months ended September 30, 2009 and 2008, respectively. The increase in Domestic's net sales was partially the result of a 12% increase in sales in our Spine market sector, which was mainly driven by the increase in sales of our Spinal-Stim[®] and Cervical-Stim[®] products. The increase in Domestic's net sales was also attributable to the 13% increase in our Orthopedics market sector which included an 18% increase in sales of Physio-Stim[®] products as compared to the prior year period. Also contributing to the growth in the Orthopedics market is a 9% growth in our external fixation product sales.

Domestic Sales by Market Sector:

**Net Sales for the
Nine Months Ended September
30,**

(US\$ in thousands)	2009	2008	Growth
Spine	\$ 117,034	\$ 104,143	12%
Orthopedics	38,620	34,254	13%

Total	\$	155,654	\$	138,397	12%
-------	----	---------	----	---------	-----

Table of Contents

Net sales in Spinal Implants & Biologics increased \$5.5 million to \$86.6 million for the nine months ended September 30, 2009 compared to \$81.1 million for the same period last year, an increase of 7%. Spinal Implants & Biologics net sales represented 22% and 21% of total net sales during the nine months ended September 30, 2009 and 2008, respectively. Sales of our thoracolumbar products increased 10% when compared to the same period last year due to the introduction of our new Firebird pedicle screw system earlier this year. In addition, the increase in sales was also attributed to a 5% growth in Biologics product sales, which included sales from the full market release of the Trinity® Evolution stem cell-based allograft during the third quarter of 2009. All of Spinal Implants & Biologics sales are recorded in our Spine market sector.

Net sales in Breg increased \$3.8 million to \$70.2 million during the nine months ended September 30, 2009 compared to \$66.3 million for the same period last year, an increase of 6%. Breg's net sales represented 17% of total net sales during the nine months ended September 30, 2009 and 2008. The increase in Breg's net sales was primarily due to a 10% increase in sales of our Breg bracing products when compared to the same period in the prior year, primarily as a result of the sales of our new products which include spine bracing. Further, sales of our cold therapy products increased 6% over the same period in the prior year which was due to the introduction of our Kodiak® cold therapy products earlier this year. These increases were partially offset by a decrease in sales of our pain therapy products as a result of the sale of operations related to our Pain Care® line of ambulatory infusion pumps during March 2008. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International decreased 12% to \$89.2 million for the nine months ended September 30, 2009 compared to \$101.5 million for the same period last year. International's net sales represented 22% and 26% of our total net sales for the nine months ended September 30, 2009 and 2008, respectively. The impact of foreign currency decreased International net sales by 15% or \$13.8 million, during the nine months ended September 30, 2009 as compared to the same period last year. On a constant currency basis, Spine and Orthopedics sales in our International segment increased 13% and 5%, respectively, for the nine months ended September 30, 2009 when compared to the prior year. Within the Orthopedics sector, external fixation, stimulation, and deformity correction sales increased 8%, 24% and 33%, respectively, on a constant currency basis, when compared with the same period last year. Sales in our Vascular sector, which consist of the A-V® Impulse System, and our Other distributed products, primarily the Laryngeal Mask, decreased 1% and 9%, respectively, on a constant currency basis when compared to the prior year.

International Sales by Market Sector:

(US\$ in thousands)	Net Sales for the Nine Months Ended September 30,		Reported Growth	Constant Currency Growth
	2009	2008		
Spine	\$ 1,399	\$ 1,252	12%	13%
Orthopedics	56,848	62,665	-9%	5%
Sports Medicine	3,194	3,871	-17%	-3%
Vascular	12,574	13,391	-6%	-1%
Other	15,212	20,362	-25%	-9%
Total	\$ 89,227	\$ 101,541	-12%	1%

Table of Contents*Sales by Market Sector:*

Sales of our Spine products increased to \$205.0 million for the nine months ended September 30, 2009 compared to \$186.5 million for the same period last year. Sales of our Cervical-Stim® and Spinal-Stim® products increased 10% and 15%, respectively, for the nine months ended September 30, 2009 compared to 2008. In addition, sales of our Spinal Implants and Biologics products increased 7% over the same period in the prior year primarily due to sales in our Biologics products which included sales from the full market release of the Trinity® Evolution stem cell-based allograft. Spine product sales were 51% and 48% of our total net sales for the nine months ended September 30, 2009 and 2008, respectively.

Sales of our Orthopedics products decreased \$1.5 million to \$95.5 million for the nine months ended September 30, 2009 compared to \$96.9 million for the same period last year. On a constant currency basis, sales increased 8% compared to the same period last year due to increased sales of our Physio Stim®, external fixation, and deformity correction products. Orthopedic product sales were 24% and 25% of our total net sales for the nine months ended September 30, 2009 and 2008, respectively.

Sales of our Sports Medicine products increased 4% to \$73.4 million for the nine months ended September 30, 2009 compared to \$70.2 million for the same period last year. As discussed above, the increase of \$3.2 million is primarily due to sales of our Breg bracing and cold therapy products, offset by a decrease in our pain therapy products, which is principally attributable to the sale of operations relating to our Pain Care® line in March 2008. Sports Medicine product sales were 18% of our total net sales for the nine months ended September 30, 2009 and 2008.

Sales of our Vascular products, which consist of our A-V Impulse System®, decreased 6% to \$12.6 million for the nine months ended September 30, 2009 compared to \$13.4 million for the same period last year. On a constant currency basis, sales decreased 1% compared to the prior period. Vascular product sales were 3% and 4% of our total net sales for the nine months ended September 30, 2009 and 2008, respectively.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our Woman's Care line, decreased 25% to \$15.2 million for the nine months ended September 30, 2009 when compared to \$20.4 million for the same period last year. On a constant currency basis, sales for the nine months ended September 30, 2009 decreased 9% when compared to prior year. We distribute the Laryngeal Mask product in the United Kingdom and in Italy. We will transition out of the agreements to distribute the Laryngeal Mask product in Italy and in the United Kingdom, in October 2009 and June 2010, respectively. Other product sales were 4% and 5% of our total net sales for the nine months ended September 30, 2009 and 2008, respectively.

Gross Profit Our gross profit increased 11% to \$299.9 million for the nine months ended September 30, 2009, compared to \$270.1 million for the same period last year. Gross profit as a percent of net sales for the nine months ended September 30, 2009 was 74.7% compared to 69.7% for the same period last year. In the nine months ended September 30, 2008, due to reduced projections in revenue, distributor terminations, new products, and the replacement of one of our products with a successor product, the Company changed its estimates regarding the inventory allowance at Blackstone, primarily based on estimated net realizable value using assumptions about future demand and market conditions. The change in estimate resulted in an increase in the reserve for obsolescence of approximately \$10.9 million. In addition, the Company recorded approximately \$0.6 million of expense related to Blackstone instrumentation equipment, also as a result of the replacement of one of our products with a successor product. Gross profit, excluding the additional reserve recorded at Blackstone was 72.7% for the nine months ended September 30, 2008. Excluding the negative impacts in the prior year, the increase in the gross profit is primarily due to the increased sales of higher margin stimulation products and Spinal Implants & Biologics products. The gross margin in the nine months ended September 30, 2009 was impacted by a \$1.8 million increase in our inventory reserve, which related primarily to the remaining supply of Trinity® allograft on hand at the expiration of the Company's distribution agreement on June 30, 2009.

Table of Contents

Sales and Marketing Expense Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increases and decreases in relation to sales. Sales and marketing expense increased \$8.9 million, or 6%, to \$162.5 million for the nine months ended September 30, 2009 compared to \$153.7 million for the same period last year. As a percent of sales, sales and marketing expense was 40.5% and 39.7% for the nine months ended September 30, 2009 and 2008, respectively. The increase in sales and marketing expense as a percent of sales was due primarily to an increase in commission expenses reflecting the implementation of sales programs with new distributor partners. This increased investment in sales and marketing has facilitated the development of new customer relationships and increased sales, and has directly contributed to the improvement in the year-over-year operating profit margin in the Domestic segment.

General and Administrative Expense General and administrative expense increased \$4.4 million, or 7%, for the nine months ended September 30, 2009 to \$64.7 million compared to \$60.3 million for the same period last year. The increase is primarily due to a restructuring charge to consolidate substantially all of Blackstone's current operations in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and US orthopedics business in the Dallas, TX area. In addition, the Company also incurred legal and other professional services associated with a proxy contest with one of the Company's shareholders. The contest was settled in a special shareholder meeting on April 2, 2009. As a result, the Company does not anticipate incurring any expenses associated with this matter going forward. In addition, general and administrative expenses were also higher compared with the prior year due to infrastructure increases in some faster growing international markets. General and administrative expense as a percent of sales was 16.1% in the for the nine months ended September 30, 2009 compared to 15.5% for the same period last year.

Research and Development Expense Research and development expense increased \$6.4 million during the nine months ended September 30, 2009 to \$25.8 million compared to \$19.4 million for the same period last year. This increase is primarily the result of two collaborative arrangements with Musculoskeletal Transplant Foundation (MTF) and Intelligent Implant Systems, LLC (IIS). We incurred approximately \$3.9 million and \$1.8 million in expenses as a result of our collaboration with MTF and IIS, respectively, for the nine months ended September 30, 2009. As a percent of sales, research and development expense was 6.4% in the nine months ended September 30, 2009 compared to 5.0% for the same period last year. We do not expect to incur any further expense in 2009 related to these agreements; see Liquidity and Capital Resources for further detail.

Amortization of Intangible Assets Amortization of intangible assets decreased \$10.3 million for the nine months ended September 30, 2009 to \$4.9 million compared to \$15.2 million for the same period last year. This decrease is primarily attributed to the impairment of \$105.7 million of definite-lived intangible assets at Blackstone during the third quarter of 2008.

Impairment of Goodwill and Certain Intangible Assets In the nine months ended September 30, 2008, we incurred \$289.5 million of expense related to the impairment of goodwill and certain intangible assets. As part of our debt refinancing completed in September 2008, five year projections were prepared for Blackstone. These projections provided an indication of impairment. Accordingly, an interim impairment test was performed in accordance with ASC Topic 350 - Intangibles - Goodwill and Other (formerly known as SFAS No. 142, Goodwill and Other Intangible Assets,). Based on this interim test, we determined that the Blackstone trademark, an indefinite-lived intangible asset, was impaired by \$57.0 million. In addition, we determined that the carrying amount of goodwill related to Blackstone exceeded its implied fair value, and recognized a goodwill impairment loss of \$126.9 million.

In accordance with ASC Topic 360 - Property, Plant and Equipment (formerly known as SFAS No. 144 - Accounting for the Impairment or Disposal of Long-Lived Assets), we determined that a triggering event had occurred with respect to the definite-lived intangible assets at Blackstone. We compared the expected cash flows to be generated by the definite lived intangible on an undiscounted basis to the carrying value of the intangible asset. We determined the carrying value exceeded the undiscounted cash flow and impaired the distribution network and technologies at Blackstone to the fair value which resulted in an impairment charge of \$105.7 million.

Gain on Sale of Pain Care® Operations Gain on sale of Pain Care® operations was \$1.6 million for the nine months ended September 30, 2008 and represented the gain on the sale of operations related to our Pain Care® line of ambulatory infusion pumps during March 2008. No such gain was recorded in the same period of 2009.

Table of Contents

Interest Expense, net Interest expense, net was \$18.4 million for the nine months ended September 30, 2009 compared to \$13.7 million for the same period last year. Included in interest expense, net for the nine months ended September 30, 2009 and 2008 was interest expense of \$17.7 million and \$11.5 million related to the senior secured term loan used to finance the Blackstone acquisition. Although our overall senior secured term loan balance has decreased when compared to the same period in the prior year, our effective interest rate has increased which is generating the additional interest expense.

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

Unrealized Non-cash Gain on Interest Rate Swap In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. During the fourth quarter of 2008, the Company recognized in earnings an unrealized, non-cash loss of approximately \$(8.0) million when it was determined that the Swap was no longer deemed highly effective. Therefore, cash flow accounting is no longer applied and mark-to-market adjustments are required to be reported in current earnings through the expiration of the swap in June 2011. For the nine months ended September 30, 2009, the Company recorded an unrealized non-cash gain of \$1.0 million in other income (expense), net.

Other Income (Expense), net Other income (expense), net was an expense of \$(0.6) million for the nine months of 2009 compared to an expense of \$(2.7) million for the same period last year. The decrease can be mainly attributed to the effect of foreign exchange. During the nine months ended September 30, 2008, notably in September, we recorded foreign exchange losses of \$2.2 million principally as a result of a rapid strengthening of the US Dollar against various foreign currencies including the Euro, Pound, Peso and Brazilian Real. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the US Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies.

Income Tax Benefit (Expense) Our effective tax rate was an expense of 37.4% and a benefit of 21.0% during the nine months ended September 30, 2009 and 2008, respectively. The effective tax rate for the nine months ended September 30, 2009 included an unfavorable discrete item resulting from additions to reserves for unrecognized tax benefits. The effective tax rate benefit for the nine months ended September 30, 2008 included unfavorable discrete items resulting from the impairment of goodwill for which we receive no tax benefit and the sale of our Pain Care® operations. Excluding these discrete items, our effective tax rate was an expense of 35.4% and a benefit of (39.5%), respectively. The decrease in the effective tax rate excluding discrete items is primarily attributable to changes in the jurisdictional mix of earnings.

Net Income (Loss) Net income for the nine months ended September 30, 2009 was \$15.0 million, or \$0.88 per basic share and \$0.87 per diluted share, compared to a net loss of \$(227.8) million, or \$(13.33) per basic and diluted share for the same period last year. The weighted average number of basic common shares outstanding was 17,113,891 and 17,093,133 during the nine months ended September 30, 2009 and 2008, respectively. The weighted average number of diluted common shares outstanding was 17,174,416 and 17,093,133 during the nine months ended September 30, 2009 and 2008, respectively.

Liquidity and Capital Resources

Cash and cash equivalents at September 30, 2009 were \$20.0 million, of which \$13.2 million was subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of \$25.6 million at December 31, 2008, of which \$11.0 million was restricted.

Table of Contents

Net cash provided by operating activities was \$28.2 million for the nine months ended September 30, 2009 compared to \$2.4 million for the same period last year. Net cash provided by operating activities is comprised of net income (loss), non-cash items (including depreciation and amortization, share-based compensation, provision for doubtful accounts, provision for inventory obsolescence, impairment of goodwill and certain intangible assets, loss on refinancing of senior secured term loan, deferred taxes, and gain on the sale of Pain Care® operations) and changes in working capital, including changes in restricted cash. Net income increased \$242.8 million to \$15.0 million for the nine months ended September 30, 2009 from net loss of \$(227.8) million for the comparable period in the prior year. Non-cash expense for the nine months ended September 30, 2009 decreased \$235.5 million compared to the same period last year primarily as a result of the impairment of goodwill and certain intangible assets of \$289.5 million during the nine months ended September 30, 2008 that did not exist in the current year, a decrease in the provision for inventory obsolescence of \$6.9 million, and a decrease in depreciation and amortization of \$6.6 million, offset by an increase in the change in deferred taxes of \$74.8 million. Working capital accounts consumed \$20.7 million of cash in the nine months ended September 30, 2009 compared to \$39.1 million for the same period last year. The principal change in working capital can be mainly attributable to an increase in the current liabilities position of \$17.5 million mainly the result of restructuring costs previously mentioned, increases in accrued payroll, bonuses and related payroll taxes, increased commissions to distributors and the timing of inventory receipts near the end of the period. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 87 days at September 30, 2009 compared to 82 days at September 30, 2008 and inventory turns of 1.3 times at September 30, 2009 compared to 2.0 times at September 30, 2008. Excluding the impact of the \$11.5 million spinal implants inventory reserve taken in the third quarter of 2008, the inventory turns were 1.5. Also included in cash used in working capital during the nine months ended September 30, 2009 were \$5.6 million in costs related to matters occurring at Blackstone prior to the acquisition and for which we are seeking reimbursement from the applicable escrow fund.

Net cash used in investing activities was \$14.4 million during the nine months ended September 30, 2009 compared to \$9.1 million provided by investing activities during the same period last year. During the first quarter of 2008, we sold the operations of our Pain Care® line of ambulatory infusion pumps for net proceeds of \$6.0 million. During the nine months ended September 30, 2009 and 2008, we invested \$16.1 million and \$15.8 million in capital expenditures, respectively. During the nine months ended September 30, 2009, we sold our remaining ownership in OPED AG, a German based bracing company, for net proceeds of \$1.7 million. During the nine months ended September 30, 2008, we sold a portion of our ownership in OPED AG for net proceeds of \$0.8 million.

Net cash used in financing activities was \$22.0 million for the nine months ended September 30, 2009 compared to \$7.6 million for the same period last year. During the nine months ended September 30, 2009, we repaid approximately \$22.5 million against the principal on our senior secured term loan compared to \$6.2 million during the nine months ended September 30, 2008. During the nine months ended September 30, 2009, we borrowed \$1.6 million on our line of credit through our Italian subsidiary compared to a repayment on that same line of credit of \$2.4 million for the same period in the prior year. During the nine months ended September 30, 2009, we used approximately \$1.1 million to purchase an additional 32% minority interest in our Breg distributor in Germany. During the nine months ended September 30, 2008, we received proceeds of \$1.7 million from the issuance of 51,052 shares of our common stock upon the exercise of stock options.

On September 22, 2006 the Company's wholly-owned US holding company subsidiary, Orthofix Holdings, Inc. (Orthofix Holdings), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. Certain terms of the senior secured credit facility were amended in September 29, 2008. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of \$330.0 million and (2) a six-year revolving credit facility of \$45.0 million. As of September 30, 2009, the Company had no amounts outstanding under the revolving credit facility and \$258.2 million outstanding under the term loan facility. Obligations under the senior secured credit facility can have a floating interest rate of the London Inter-Bank Offered Rate (LIBOR) plus a margin, with a LIBOR floor of 3.0%, or prime rate plus a margin. As of September 30, 2009, the entire term loan obligation of \$258.2 million is at the prime rate plus a margin of 3.50%.

In June 2008, we entered into a three-year fully amortizable interest rate swap agreement (the Swap) with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of September 30, 2009 was \$150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of September 30, 2009, the effective interest rate on the debt related to the Swap was 10.6%. Our overall effective interest rate, including the impact of the Swap as of September 30, 2009 on our senior secured debt was 9.0%.

Table of Contents

The credit agreement contains certain financial covenants, including a fixed charge coverage ratio and a leverage ratio applicable to Orthofix and its subsidiaries on a consolidated basis. A breach of any of these covenants could result in an event of default under the credit agreement, which could permit acceleration of the debt payments under the facility. The Company was in compliance with these financial covenants as measured at September 30, 2009. As defined in the senior secured credit facility, our leverage ratio can not exceed 3.50 and our fixed charge ratio must be greater than or equal to 1.30. At September 30, 2009, our leverage and fixed charge ratios were 2.93 and 1.50, respectively.

The leverage ratio the Company can not exceed, as defined in the senior secured credit facility, will be 3.25 for the fourth quarter of 2009, 2.85 for the first quarter of 2010, 2.75 for the second quarter of 2010 and 2.50 thereafter. The fixed charge coverage ratio must be greater than 1.30. This remains in effect for the rest of 2009. Effective January 1, 2010, this ratio will increase to 1.375 and remain at that rate for the remaining life of the senior secured credit facility. Based on the Company's projected earnings, we believe that the Company should be able to meet these financial covenants in future fiscal quarters, however, there can be no assurance that it will be able to do so, and failure to do so could result in an event of default under the credit agreement, which could have a material adverse effect on our financial position.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's senior secured credit facility. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of September 30, 2009 is \$130.8 million compared to \$111.3 million at December 31, 2008. In addition, the senior secured credit facility restricts the Company and subsidiaries that are not parties to the credit facility from access to cash held by Colgate Medical Limited and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of September 30, 2009 is \$13.2 million compared to \$11.0 million at December 31, 2008.

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

At September 30, 2009, we had outstanding borrowings of \$3.7 million and unused available lines of credit of approximately 4.8 million Euro (\$7.0 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

In the fourth quarter of 2008, as part of the Company's strategic plan to strengthen the business, the Company initiated a restructuring plan to improve operations and reduce costs at Blackstone. The plan involves the consolidation of substantially all of Blackstone's current operations in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and US orthopedics business in the Dallas, TX area. The Company plans to complete the restructuring and consolidation by the second quarter of 2010, at which time the Company anticipates a total restructuring expense of \$3.6 million. During the three and nine months ended September 30, 2009, the Company recorded net restructuring charges of \$0.6 million and \$3.6 million, respectively, which were primarily related to severance costs and accelerated depreciation costs related to shortening lives of assets which will be disposed. These restructuring costs are recorded in general and administrative expense and are classified in the Spinal Implants & Biologics segment.

Table of Contents

The following table presents changes in the restructuring liability, which is included within Other Current Liabilities in the Company's condensed consolidated balance sheets as of September 30, 2009 and December 31, 2008:

(US\$ in thousands)	Severance	Assets Abandoned	Total
Balance at December 31, 2008	\$ 548	\$	\$ 548
Charges	2,565	1,020	3,585
Cash Payments	(1,018)		(1,018)
Non-cash Items		(1,020)	(1,020)
Balance at September 30, 2009	\$ 2,095	\$	\$ 2,095

On July 24, 2008, we entered into an agreement with Musculoskeletal Transplant Foundation (MTF) to collaborate on the development and commercialization of a new stem cell-based bone growth biologic matrix. Under the terms of the agreement, we have invested \$10.0 million to develop the new stem cell-based bone growth biologic matrix that provides the beneficial properties of an autograft in spinal and orthopedic surgeries. With the development process now complete, the Company and MTF operate under the terms of a separate commercialization agreement. Under the terms of this 10-year agreement, MTF sources the tissue, processes it to create the bone growth matrix, and packages and delivers it in accordance with orders received directly from customers and from the Company. The Company has exclusive global marketing rights for the new allograft and receives a marketing fee from MTF based on total sales. We follow the authoritative accounting guidance for collaborative arrangements. The new matrix was launched with a full market release in the US effective on July 1, 2009. A total of \$3.9 million of expenses incurred under the terms of the agreement are included in research and development expense in the nine months ended September 30, 2009.

As previously announced in 2008, we entered into an agreement with Intelligent Implant Systems (IIS) for the acquisition and development of a next-generation pedicle screw system for our spinal implants division. Under the agreement we purchased \$2.5 million of intellectual property and related technology. During the nine months ended September 30, 2009, IIS met their first development milestone and under the terms of the agreement the Company paid IIS \$1.0 million. During the third quarter of 2009, the Company and IIS amended the existing agreement and the Company paid IIS an additional \$0.8 million for partially meeting its next milestone. The Company has recorded these payments totaling \$1.8 million for the nine months ended September 30, 2009 as research and development expense. IIS will continue to perform research and development functions related to the technology and under the agreement and amended agreement we will pay IIS an additional amount up to \$2.7 million for research and development performance milestones.

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

Table of Contents**ORTHOFIX INTERNATIONAL N.V.****Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations, and the cost of financing and yields on cash and short-term investments. We use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of September 30, 2009, we had a currency swap in place to minimize foreign currency exchange risk related to a 38.3 million Euro intercompany note.

We are exposed to interest rate risk in connection with our senior secured term loan and borrowings under our revolving credit facility (if any), which bear interest at floating rates based on LIBOR or the prime rate plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant. We had an interest rate swap in place as of September 30, 2009 to minimize interest rate risk related to our LIBOR-based borrowings.

As of September 30, 2009, we had \$258.2 million of variable rate term debt represented by borrowings under our senior secured term loan which can have a floating interest rate of LIBOR plus a margin, with a LIBOR floor of 3.0%, or the prime rate plus a margin. As of September 30, 2009, the entire term loan obligation of \$258.2 million is at the prime rate plus a margin of 3.50%, which is adjusted based upon the credit rating of the Company and its subsidiaries. In June 2008, we entered into a Swap with a notional amount of \$150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of September 30, 2009 was \$150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of September 30, 2009, the effective interest rate on the debt related to the Swap was 10.6%. As of September 30, 2009, our overall effective interest rate, including the impact of the Swap, on our senior secured debt was 9.0%. Based on the balance outstanding under the senior secured term loan combined with the Swap as of September 30, 2009, an immediate change of one percentage point in the applicable interest rate on the variable rate debt would cause a change in interest expense of approximately \$1.9 million on an annual basis.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the US 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 US 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, 2009, we had an un-hedged intercompany receivable denominated in Euro of approximately 22.8 million (\$33.3 million). We recorded a foreign currency gain during the nine months ended September 30, 2009 of \$1.5 million, which resulted from the strengthening of the Euro against the US dollar during the period.

We also are subject to currency exposure from translating the results of our global operations into the US dollar at exchange rates that have fluctuated from the beginning of the period. The US dollar equivalent of international sales denominated in foreign currencies was unfavorably impacted during the nine months ended September 30, 2009 by foreign currency exchange rate fluctuations with the strengthening of the US dollar against the local foreign currency during this period. The US dollar equivalent of the related costs denominated in these foreign currencies was favorably impacted during this period. During the nine months ended September 30, 2008, the US dollar equivalent of international sales denominated in foreign currencies was favorably impacted by foreign currency exchange rate fluctuations with the weakening of the US dollar against the local foreign currency during this period. The US dollar equivalent of the related costs denominated in these foreign currencies was unfavorably impacted during this period. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results.

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

On July 1, 2009, we implemented an Enterprise Resource Planning (ERP) system at our Spinal Implants & Biologics division. The ERP system, developed by Oracle, is expected to improve and enhance internal controls over financial reporting. This ERP system materially changes how transactions are processed within this division.

Except for the conversion to the ERP system, there have not been any changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

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

On or about January 7, 2008, the Company received a federal grand jury subpoena from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with the Department of Health and Human Services, Office of Inspector General's investigation of such matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On or about April 29, 2009, counsel for the Company received a HIPAA subpoena issued by the US 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 June 15, 2009, Orthofix, Inc., and Blackstone, executed an agreement with the United States Attorney's Office for the District of Massachusetts (the Tolling Agreement) extending an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate. The Tolling Agreement extended the period tolling the statute of limitations to include the period from December 1, 2008 through and including December 31, 2009.

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 US 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 US Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. On November 21, 2008, the US Department of Justice filed a notice of non-intervention in the case. The complaint was served on Blackstone on or about March 24, 2009. Counsel for the plaintiffs filed an amended complaint on June 4, 2009. The amended complaint sets forth a cause of action against Blackstone under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants; Orthofix is not named as a defendant in the amended complaint. The Company believes that this lawsuit is related to the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and the United States Attorney's Office for the District of Massachusetts. The Company intends to defend vigorously against this lawsuit. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of the US Department of Justice and prior to the unsealing of the complaint (which was unsealed by the court on or about November 24, 2008), the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter.

Table of Contents

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

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

Under the Blackstone Merger Agreement, the former shareholders of Blackstone have agreed to indemnify the Company for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders are limited to a cumulative aggregate amount of \$66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was \$50.0 million. As of September 30, 2009, the escrow fund, which has subsequently accrued interest, contained \$54.0 million. The Company is also entitled to seek direct personal recourse against certain principal shareholders of Blackstone after all monies on deposit in the escrow fund have been paid out or released or are the subject of pending or unresolved indemnification claims but only for a period of six years from the closing date of the Merger and only up to an amount equal to \$66.6 million less indemnification claims previously paid.

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

The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund and there can be no assurance that losses to the Company from these matters will not exceed the amount of the escrow fund. Expenses incurred by the Company relating to the above matters are recorded as an escrow receivable in the Company's financial statements to the extent the Company believes, among other things, that collection of the claims is reasonably assured. Expenditures related to such matters for which the Company believes collection is doubtful are recognized in earnings when incurred. As of September 30, 2009 and December 31, 2008, included in Prepaid expenses and other current assets is approximately \$13.3 million and \$8.3 million, respectively, of escrow receivable

balances related to the Blackstone matters described above. These amounts include, among other things, attorneys' fees and costs related to the government investigations manifested by the subpoenas described above, the stock option-related claims described above, and costs related to the qui-tam action described above. As described above, some of these reimbursement claims are being contested by the representative of the former shareholders of Blackstone. To mitigate the risk that some reimbursement claims will not be collected, the Company records a reserve against the escrow receivable during the period in which reimbursement claims are recognized.

Table of Contents

On or about April 10, 2009, the Company received a HIPAA subpoena (HIPAA subpoena) issued by the US Attorney s Office for the District of Massachusetts. The subpoena seeks documents for the period January 1, 1995 through the date of the subpoena. The Company believes that the subpoena concerns the classification and marketing of its bone growth stimulators and related matters. On or about September 21, 2009, the Company received an additional HIPAA subpoena issued by the U.S. Attorney s Office for the District Of Massachusetts in connection with this investigation. The subpoena seeks additional documents pertaining to the investigation for the period January 1, 1995 through the date of the subpoena. The Company intends to cooperate with the government s requests. The Company is unable to predict what actions, if any, might be taken by the government or what impact, if any, the outcome of this matter might have on the Company s consolidated financial position, results of operations or cash flows.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the US District Court for the District of Massachusetts against Orthofix, Inc., the Company, and other companies that have allegedly manufactured bone growth stimulation devices, including Orthologic Corp., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. By order entered on March 24, 2009, the court unsealed the case. The amended 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 amended complaint also includes claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-kickback Act by providing free products to physicians, waiving patients insurance co-payments, and providing inducements to independent sales agents to generate business. The Company believes that this lawsuit is related to the matter described above involving the HIPAA subpoena. The Company and Orthofix, Inc. were served on or about September 8, 2009, and intend to defend vigorously against this lawsuit.

On or about July 2, 2009, the Company obtained a copy of a qui tam complaint filed by Marcus Laughlin that is pending in the US District Court for the District of Massachusetts against the Company. This complaint has been consolidated with the complaint described in the immediately preceding paragraph, and was unsealed on June 30, 2009. The complaint alleges violations of the False Claims Act, fraudulent billing, illegal kickbacks and wrongful termination based on allegations that the Company promoted the sale rather than the rental of bone growth stimulation devices, systematically overcharged for these products, provided physicians kickbacks in the form of free units, referral fees, and fitting fees, and that the defendant and its competitors discussed together strategies to encourage higher government pricing for the products. The complaint also alleges that TRICARE has been reimbursing the Company for its Cervical Stim® product without approval to do so. An amended complaint alleges conspiracy and violations of the Sherman Anti-Trust Act in connection with the same alleged conduct. The Company was served with the complaint on or about September 9, 2009 and intends to defend vigorously against this lawsuit.

Table of Contents

Effective October 29, 2007, Blackstone entered into a settlement agreement of a patent infringement lawsuit brought by certain affiliates of Medtronic Sofamor Danek USA Inc. In that lawsuit, the Medtronic plaintiffs had alleged that they were the exclusive licensees of certain US patents and that Blackstone's making, selling, offering for sale, and using its Blackstone Anterior Cervical Plate, 3° Anterior Cervical Plate, Hallmark Anterior Cervical Plate 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 Company's consolidated financial position, results of operations or cash flows. On July 20, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. The Company was subsequently notified by legal counsel of the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

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

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

Item 1A. Risk Factors

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, 2008.

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
3.2	Articles of Association of the Company as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
10.1	Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended (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).
10.2	Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference).
10.3	Orthofix International N.V. Staff Share Option Plan, as amended through April 22, 2003 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007 and incorporated herein by reference).
10.4	Form of Employee Non-Qualified Stock Option Agreement (post-2008 grants) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.5	Form of Non-Employee Director Non-Qualified Stock Option Agreement (post-2008 grants) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.6	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants - vesting over 3 years) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.7	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants - 3 year cliff vesting) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.8	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (vesting over 3 years) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.9	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff vesting) (filed as an exhibit to the

Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).

- 10.10 Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company's current report on Form 8-K filed January 7, 2009, and incorporated herein by reference).

Table of Contents

Exhibit Number	Description
10.11	Acquisition Agreement dated as of November 20, 2003, among Orthofix International N.V., Trevor Acquisition, Inc., Breg, Inc. and Bradley R. Mason, as shareholders representative (filed as an exhibit to the Company's current report on Form 8-K filed January 8, 2004 and incorporated herein by reference).
10.12	Amended and Restated Voting and Subscription Agreement dated as of December 22, 2003, among Orthofix International N.V. and the significant shareholders of Breg, Inc. identified on the signature pages thereto (filed as an exhibit to the Company's current report on Form 8-K filed on January 8, 2004 and incorporated herein by reference).
10.13	Amendment to Employment Agreement dated December 29, 2005 between Orthofix Inc. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed December 30, 2005 and incorporated herein by reference).
10.14	Form of Indemnity Agreement (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2008 and incorporated herein by reference).
10.15	Settlement Agreement dated February 23, 2006, between Intavent Orthofix Limited, a wholly-owned subsidiary of Orthofix International N.V. and Galvin Mould (filed as an exhibit to the Company's annual report on Form 8-K filed on April 17, 2006 and incorporated herein by reference).
10.16	Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.17*	Letter Agreement, dated July 25, 2009, between Orthofix Inc. and Raymond C. Kolls.
10.18	Credit Agreement, dated as of September 22, 2006, among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, the several banks and other financial institutions as may from time to time become parties thereunder, and Wachovia Bank, National Association (filed as an exhibit to the Company's current report on Form 8-K filed September 27, 2006 and incorporated herein by reference).
10.19	First Amendment to Credit Agreement, dated September 29, 2008, by and among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, and Wachovia Bank, National Association, as administrative agent on behalf of the Lenders under the Credit Agreement (filed as an exhibit to the Company's current report on Form 8-K filed September 29, 2008 and incorporated herein by reference).
10.20	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).

Table of Contents

Exhibit Number	Description
10.21	Employment Agreement, dated as of September 22, 2006, between Blackstone Medical, Inc. and Matthew V. Lyons (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2006, as amended, and incorporated herein by reference).
10.22	Amended and Restated Employment Agreement dated December 6, 2007 between Orthofix Inc. and Timothy M. Adams (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.23	Nonqualified Stock Option Agreement between Timothy M. Adams and Orthofix International N.V. dated November 19, 2007 (filed as an exhibit to the Company's current report on Form 8-K filed November 21, 2007 and incorporated herein by reference).
10.24	Employment Agreement between Orthofix Inc. and Scott Dodson, dated as of December 10, 2007 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).
10.25	Description of Director Fee Policy (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2009 and incorporated herein by reference).
10.26	Summary of Orthofix International N.V. Annual Incentive Program (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2009 and incorporated herein by reference).
10.27	Employment Agreement between Orthofix Inc. and Thomas Hein dated as of April 11, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).
10.28	Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan, dated April 11, 2008, between Orthofix International N.V. and Thomas Hein (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).
10.29	Summary of Consulting Arrangement between Orthofix International N.V. and Peter Hewett (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).
10.30	Employment Agreement between Orthofix Inc. and Denise E. Pedulla dated as of June 9, 2008 (filed as an exhibit to the company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
10.31	Form of Inducement Grant Nonqualified Stock Option Agreement between Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the current report on Form 8-K of Orthofix International N.V. dated September 10, 2008 and incorporated herein by reference).
10.32+	Letter Agreement between Orthofix Inc. and Oliver Burckhardt dated August 28, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30,

Table of Contents

Exhibit Number	Description
10.33	Notice of Termination from Orthofix Inc. to Oliver Burckhardt dated August 27, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference).
10.34	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).
10.35	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).
10.36	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).
10.37*	Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Alan W. Milinazzo.
10.38	Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.39*	Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Robert S. Vaters.
10.40	Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Bradley R. Mason (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.41*	Amendment No. 1 to Amended and Restated Employment Agreement, dated July 31, 2009, by and between Orthofix Inc. and Bradley R. Mason.
10.42*	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.
10.43	Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.44*	Amendment No. 1 to Amended and Restated Employment Agreement, dated August 4, 2009, by and between Orthofix Inc. and Michael M. Finegan.
10.45	Form of Amendment to Stock Option Agreements (for Alan W. Milinazzo, Robert S. Vaters, Bradley R. Mason, and Michael M. Finegan) (filed as an exhibit to the Company's current report

on Form 8-K filed July 7, 2009 and incorporated herein by reference).

- 10.46 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).

Table of Contents

Exhibit Number	Description
10.47	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).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1*	Section 1350 Certification of Chief Executive Officer.
32.2*	Section 1350 Certification of Chief Financial Officer.

* Filed herewith.

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

Table of Contents

SIGNATURES

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

ORTHOFIX INTERNATIONAL N.V.

Date: November 6, 2009

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

Date: November 6, 2009

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
10.17*	Letter Agreement, dated July 25, 2009, between Orthofix Inc. and Raymond C. Kolls.
10.37*	Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Alan W. Milinazzo.
10.39*	Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Robert S. Vaters.
10.41*	Amendment No. 1 to Amended and Restated Employment Agreement, dated July 31, 2009, by and between Orthofix Inc. and Bradley R. Mason.
10.42*	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.
10.44*	Amendment No. 1 to Amended and Restated Employment Agreement, dated August 4, 2009, by and between Orthofix Inc. and Michael M. Finegan.
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1*	Section 1350 Certification of Chief Executive Officer.
32.2*	Section 1350 Certification of Chief Financial Officer.

* Filed herewith.