

# Orthofix International Announces Record Revenue in 2nd Quarter 2009

- Q209 sales totaled a record \$137.5 million, up 6% from Q208; up 10% on a constant currency basis
- Sales of spinal implants & biologics were \$30.6 million, up 12% vs. prior year
- Q209 reported net income was \$0.35 per diluted share; excluding certain items, adjusted net income was \$0.42 per diluted share, which was 17% higher than the prior year
- Full market introduction of Trinity<sup>(R)</sup> Evolution<sup>(TM)</sup> began July 1<sup>st</sup>
- Company made \$5 million debt repayment ahead of scheduled maturity in July

BOSTON, Jul 30, 2009 (BUSINESS WIRE) -- Orthofix International N.V. (NASDAQ:OFIX) (the Company) today announced its results for the second quarter ended June 30, 2009. Total quarterly revenue was a record \$137.5 million, which was an increase of 6% over the second quarter of 2008. Excluding the unfavorable \$5.5 million impact of foreign currency on second quarter sales, revenue increased 10% on a constant currency basis.

Reported second quarter net income totaled \$5.9 million, or \$0.35 per share. This compared with \$5.8 million, or \$0.34 per share in the second quarter of the prior year. Excluding certain items summarized in the table below, second quarter adjusted net income was \$7.2 million, or \$0.42 per share, which was 17% higher than adjusted net income of \$6.3 million, or \$0.36, in the prior year.

"I'm very pleased to report a strong quarter, which is reflected in our consolidated revenue and earnings results. These favorable results were consistent across all of our core business segments. This included our spinal implant business, which continued to gain momentum in the second quarter as sales grew 12% led by the recent launches of our Firebird<sup>(TM)</sup> pedicle screw system, Pillar<sup>(TM)</sup> SA interbody device and Trinity<sup>(R)</sup> Evolution<sup>(TM)</sup> stem cell-based allograft," said President and CEO Alan Milinazzo. "Additionally, our improved cash flow has allowed us to make a total of \$20 million in debt payments ahead of their scheduled maturities so far this year, including a \$5 million payment this month. Based on our results for the first half of 2009 we are reaffirming our full-year guidance."

## **Non-GAAP Performance Measures**

The table below presents a reconciliation of second quarter net income calculated in accordance with generally accepted accounting principles (GAAP) to a non-GAAP performance measure, referred to as "adjusted net income", that excludes from net income the items specified in the table. Additionally a reconciliation between second quarter net income calculated in accordance with GAAP and the non-GAAP measure referred to as "Consolidated EBITDA" is included in the Regulation G Supplemental Information Schedule attached to this release. Management believes it is important to provide investors with the same non-GAAP metrics it uses to supplement information regarding the performance and underlying trends of Orthofix's business operations in order to facilitate comparisons to its historical operating results and internally evaluate the effectiveness of the Company's operating strategies. A more detailed explanation of the items in the table below that are excluded from GAAP net income, as well as why management believes the non-GAAP measures are useful to them, is included in the Regulation G Supplemental Information schedule attached to this press release.

# **Reconciliation of Non-GAAP Performance Measure**

Second Quarter	Q209	Q208			
	(\$000's) EPS	(\$000's) EPS			
Reported GAAP net income	\$ 5,944 \$ 0.35	\$ 5,808 \$ 0.34			
Specified Items:					
Strategic investments	\$ 1,365 \$ 0.08	\$ 516 \$ 0.03			
Reorganization/consolidation costs	\$ 1,075 \$ 0.06	\$ 371 \$ 0.02			
Foreign exchange (gain)/loss	(\$509) (\$0.03	) (\$431) (\$0.03)			
Unrealized, non-cash gain on interest rate swap	(\$674) (\$0.04	)			
Adjusted net income	\$ 7,201 \$ 0.42	\$ 6,264 \$ 0.36			

NOTE: Some calculations may be impacted by rounding

# **Revenue**

Total second quarter sales in the Company's spine sector were up 13% year-over-year, to a record \$70.7 million. Spine stimulation revenue increased 13%, to \$40.1 million due to the continued success of the Company's devices, including the only FDA-approved stimulator for the cervical spine. Spinal implant and biologic revenue was \$30.6 million, which was 12% higher than the second quarter of 2008. The year-over-year growth in implant and biologic revenue was primarily due to an 11% increase in U.S. sales of thoracolumbar and cervical spine implant devices, and 12% growth in biologic revenue. The growth in sales of thoracolumbar and cervical spine implant

devices was driven primarily by the Company's recent introductions of its new Firebird<sup>(TM)</sup> pedicle screw system and Pillar<sup>(TM)</sup> SA interbody device. The increase in biologic revenue from our spinal implants division included \$743,000 in sales from the limited market release of the Company's new Trinity<sup>(R)</sup> Evolution<sup>(TM)</sup> stem cell-based allograft. After initiating the limited market release of Trinity<sup>(R)</sup> Evolution<sup>(TM)</sup> on May 1<sup>st</sup>, Orthofix began the full market release of its new allograft, which was developed in collaboration with the Musculoskeletal Transplant Foundation (MTF), on July 1<sup>st</sup>.

Reported second quarter revenue in the Company's orthopedic business was \$32.6 million, which was a decrease of 2%, but represented growth of 9% on a constant currency basis, compared with the prior year. The constant currency revenue growth was driven primarily by increases in international sales of external and internal fixation devices of 13% and 6%, respectively, as well as 14% global growth in the sales of Physio-Stim<sup>(TM)</sup> bone growth stimulation devices. Additionally, sales of our biologics products in the Orthopedic Division almost doubled to approximately \$1.7 million, which included \$1.4 million in sales of Trinity and \$164,000 in sales of Trinity Evolution.

Sports medicine revenue in the second quarter grew 5% compared with 2008, to a record \$24.5 million. This growth was driven primarily by an 11% increase in U.S. revenue from the Company's core bracing products, which was a reflection of the recent expansion of certain product lines, including soft goods and spine bracing, as well as those for the upper extremities and the ankles and feet.

### **Gross Margin**

The gross profit margin in the second quarter of 2009 was 73.2%, which was 20 basis points higher than the second quarter of 2008. The gross margin in the second quarter of 2009 included the impact of a \$1.8 million increase in Orthofix's inventory reserve, which related primarily to the supply of Trinity<sup>(R)</sup> allograft remaining on hand at the expiration of the Company's distribution agreement on June 30th. The year-over-year improvement is primarily due to an increased mix of revenue from the Company's higher margin spine stimulation and spinal implants businesses.

# **Operating Expenses**

Second quarter sales and marketing (S&M) expenses as a percent of revenue decreased 70 basis points year-over-year, to 40.2%. The lower S&M ratio was due primarily to a reduction in costs associated with the sales force and sales administration at the Company's spinal implants division.

General and administrative (G&A) expenses in the second quarter of 2009 increased by 100 basis points year-over-year, to 15.4% of sales. This included the impact of approximately \$1.7 million (\$1.1 million net of tax, or \$0.06 per share) in costs associated with the ongoing reorganization and consolidation plan at the Company's spinal implants business.

Research and development (R&D) expenses as a percent of revenue were 6.5% in the second quarter of 2009, compared with 5.1% in the prior year. R&D expenses in the second quarter of 2009 included the final \$2.1 million (\$1.4 million net of tax, or \$0.08 per share) in costs associated with the Company's previously announced \$10 million strategic investment in the collaboration with the Musculoskeletal Transplant Foundation (MTF) on the development and commercialization of Trinity Evolution.

### Other Income and Expenses

Second quarter net interest expense was \$5.8 million, compared with net interest expense of approximately \$4.1 million in the second quarter of the prior year. The increase reflects a higher rate of interest partially offset by a lower outstanding debt balance compared with the prior year.

During the second quarter, the Company also incurred an unrealized, non-cash gain of approximately \$1 million (\$674,000 net of tax, or \$0.04 per share) which resulted from changes in the fair value of the Company's interest rate swap.

Mark-to-market adjustments related to this swap are required to be reported in quarterly earnings through the expiration of the swap in June 2011.

The Company also incurred a foreign exchange gain of approximately \$800,000 (\$509,000 net of tax, or \$0.03 per share) in the second quarter primarily due to unrealized, non-cash foreign currency adjustments resulting from a strengthening of the U.S. dollar against various foreign currencies. A number of Orthofix's foreign subsidiaries have intercompany and trade accounts payable that are denominated in currencies, most notably the U.S. Dollar, other than their local currency, and movements in the relative values of those currencies have and are expected to continue to result in foreign exchange gains and losses.

# **Taxes**

The reported tax rate in the second quarter of 2009 was 36%. This was higher than the tax rate of 28% in the second quarter of 2008, which included the impact of lower projected taxable earnings from U.S.-sourced income which carries a higher tax rate than foreign-sourced income. The year-to-date tax rate is 35%.

# **Cash and Liquidity**

Orthofix's Consolidated EBITDA, as calculated in accordance with the Company's amended credit facility, was \$23.5 million in the second quarter. At the end of the second quarter the Company's leverage ratio, as defined in its amended credit facility, was 3.6, which was below

the 4.0 maximum leverage ratio allowed in the amended credit facility. Cash flow from operations in the second quarter of 2009 was approximately \$5.9 million, which was greater than cash flow of approximately \$1.4 million in the prior year. The increase in cash flow was due primarily to improved working capital management. Orthofix continues to have a \$45 million unused revolving credit facility, and at the end of the second quarter the Company was in compliance with the financial covenants contained in its amended credit agreement.

The total cash balance of \$21.5 million at June 30, 2009 compared with \$25.6 million at December 31, 2008. The change in cash balance includes the impact of two previously announced first quarter repayments and one second quarter repayment of debt ahead of their scheduled maturities totaling \$15 million.

# **Conference Call**

Orthofix will host a conference call today at 4:30 PM Eastern time to discuss the Company's financial results for the second quarter. Interested parties may access the conference call by dialing (866) 626-7622 in the U.S., and (706) 758-3283 outside the U.S., and providing the conference ID 20357652. A replay of the call will be available for one week by dialing (800) 642-1687 in the U.S., and (706) 645-9291 outside the U.S., and entering the conference ID 20357652.

### **About Orthofix**

Orthofix International, N.V. is a global medical device company offering a broad line of minimally invasive surgical, and non-surgical, products for the spine, orthopedic, and sports medicine market sectors that address the lifelong bone-and-joint health needs of patients of all ages-helping them achieve a more active and mobile lifestyle. Orthofix's products are widely distributed around the world to orthopedic surgeons and patients via Orthofix's sales representatives and its subsidiaries, including BREG, Inc. and Blackstone Medical, Inc., and via partnerships with other leading orthopedic product companies. In addition, Orthofix is collaborating in R&D partnerships with leading medical institutions such as the Musculoskeletal Transplant Foundation, the Orthopedic Research and Education Foundation, Rutgers University and the National Osteoporosis Institute. For more information about Orthofix, please visit <a href="https://www.orthofix.com">www.orthofix.com</a>.

### FORWARD-LOOKING STATEMENTS

This communication contains certain forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements, which may include, but are not limited to, statements concerning the projections, financial condition, results of operations and businesses of Orthofix and its subsidiaries and are based on management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements.

Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to the expected sales of its products, including recently launched products, unanticipated expenditures, changing relationships with customers, suppliers, strategic partners and lenders, 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, credit markets and the economy, corporate development and market development activities, including acquisitions or divestitures, unexpected costs or operating unit performance related to recent acquisitions, unexpected difficulties meeting covenants contained in our secured bank credit facility and other factors described in our annual report on Form 10-K and other periodic reports filed by the Company with the Securities and Exchange Commission (SEC).

- Financial tables follow -

# ORTHOFIX INTERNATIONAL N.V. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited, U.S. Dollars, in thousands, except per share and share data)

	Three Months Ended June 30,			Six Months Ended June 30,		
		2009	2008		2009	2008
Net sales	\$	137,546 \$	130,039	\$	266,520 \$	258,071
Cost of sales		36,909	35,048		69,715	69,286
Gross profit	_	100,637	94,991		196,805	188,785
Operating expenses	_				_	_
Sales and marketing		55,272	53,246		107,536	103,442
General and administrative		21,191	18,779		43,875	40,959
Research and development		8,886	6,599		17,973	12,953
Amortization of intangible assets		1,643	4,830		3,276	9,873
Gain on sale of Pain Care(R) Operations		0	0		0	(1,570)
		86,992	83,454		172,660	165,657
Operating income		13,645	11,537		24,145	23,128
Other income (expense), net						
Interest expense, net		(5,832)	(4,069)		(11,948)	(9,459)
Other income, net		425	591		102	1,085

Unrealized non-cash gain on interest rate swap		1,037		0		1,275		0
Other income (expense), net	_	(4,370)	_	(3,478)	)	(10,571)	_	(8,374)
Income before minority interests and income taxes		9,275		8,059		13,574		14,754
Income tax expense	_	(3,331)	_	(2,251)	)	(4,751)	_	(5,340)
Net income	\$	5,944	\$	5,808	\$	8,823	\$	9,414
Net income per common share - basic	\$	0.35	\$	0.34	\$	0.52	\$	0.55
Net income per common share - diluted	\$	0.35	\$	0.34	\$	0.51	\$	0.55
Weighted average number of common shares outstanding - basic		17,107,084		17,090,217		17,105,323		17,088,735
Weighted average number of common shares outstanding - diluted		17,172,557		17,116,015		17,139,789		17,240,004

# ORTHOFIX INTERNATIONAL N.V. CONDENSED CONSOLIDATED BALANCE SHEETS (U.S. Dollars, in thousands)

(0.5. Dollars, ili tilousalius)				
	_	naudited		ambar 21
	J	2009	Dec	ember 31, 2008
Assets	_			
Current assets:				
Cash and cash equivalents	\$	5,918	\$	14,594
Restricted cash		15,617		10,998
Trade accounts receivable, net		119,714		110,720
Inventories, net		94,172		91,185
Deferred income taxes		19,571		17,543
Prepaid expenses and other current assets	_	32,075		29,610
Total current assets		287,067		274,650
Investments		2,095		2,095
Property, plant and equipment, net		34,226	i	32,660
Patents and other intangible assets, net		50,893		53,546
Goodwill		185,270	1	182,581
Deferred taxes and other long-term assets	_	12,235	_	15,683
Total assets	\$	571,786	\$	561,215
Liabilities and shareholders' equity				
Current liabilities:				
Bank borrowings	\$	3,080		1,907
Current portion of long-term debt		3,333		3,329
Trade accounts payable		23,749		23,865
Other current liabilities	_	54,442	_	45,894
Total current liabilities		84,604		74,995
Long-term debt		260,910		277,533
Deferred income taxes		3,940		4,509
Other long-term liabilities	-	4,680	_	2,117
Total liabilities	-	354,134	· _	359,154
Shareholders' equity:				
Common shares		1,713		1,710
Additional paid-in capital	-	171,947		167,818
		173,660		169,528
Retained earnings		38,470		29,647
Accumulated other comprehensive income	-	5,522	_	2,886
Total shareholders' equity		217,652	_	202,061
Total liabilities and shareholders' equity	\$	571,786	\$	561,215

# ORTHOFIX INTERNATIONAL N.V. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited, U.S. Dollars, in thousands)

	Six Months Ended June 30,					
	2009			2008		
Cash flows from operating activities:						
Net income	\$	8,823	\$	9,414		
Adjustments to reconcile net income to net cash provided by operating activities:						
Depreciation and amortization		10,614		14,777		
Amortization of debt costs		99		632		

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Provision for doubtful accounts	3,487	3,019
Provision for inventory obsolescence	5,055	0
Deferred taxes	(1,505)	0
Share-based compensation	5,316	4,657
Minority Interest	28	235
Amortization of step up of fair value in inventory	0	242
Gain on sale of Pain Care(R) operations	0	(1,570)
Other	938	515
Change in operating assets and liabilities:		
Restricted cash	(4,592)	4,772
Accounts receivable	(10,741)	(10,630)
Inventories	(5,655)	(16,734)
Prepaid expenses and other current assets	(2,261)	(4,486)
Accounts payable	(577)	3,250
Current liabilities	7,954	(5,839)
Net cash provided by operating activities	16,983	2,254
Cash flows from investing activities:		
Capital expenditures	(9,153)	(12,150)
Proceeds from sale of Pain Care(R) operations	0	5,980
Net cash used in investing activities	(9,153)	(6,170)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	7	1,922
Repayments of long-term debt	(16,618)	(5,351)
Proceeds from (repayments of) bank borrowings, net	1,107	(1,131)
Cash payment for purchase of minority interest in subsidiary	(1,143)	0
Tax benefit on non-qualified stock options	2	22
Net cash used in financing activities	(16,645)	(4,538)
Effect of exchange rate changes on cash	139	235
Net decrease in cash and cash equivalents	(8,676)	(8,219)
Cash and cash equivalents at the beginning of the year	14,594	25,064
Cash and cash equivalents at the end of the period	\$ 5,918 \$	16,845

# External net sales by market sector (In US\$ millions)

,	Three Months Ended June 30,						Six Months Ended June 30,					
	2009		2008	Reported Growth	Constant Currency Growth		2009	2008	•	Constant Currency Growth		
Spine						-						
Stimulation	\$ 40.2	\$	35.4	13%	13%	\$	77.5 \$	68.9	12%	13%		
Implants and Biologics	30.5		27.3	12%	12%		59.4	56.3	5%	6%		
Total Spine	70.7		62.7	13%	13%		136.9	125.2	9%	10%		
Orthopedic	32.6		33.3	-2%	9%		62.2	63.1	-1%	9%		
Sports Medicine	24.5		23.2	5%	6%		48.7	46.5	5%	6%		
Vascular	4.3		3.7	14%	20%		8.7	9.1	-5%	1%		
Other Products	5.4		7.1	-24%	-4%		10.0	14.2	-29%	-10%		
Total	\$ 137.5	\$	130.0	6%	10%	\$	266.5 \$	258.1	3%	7%		

# Regulation G Supplemental Information Schedule

The information in this schedule is set up in three sections intended to address different aspects of Regulation G.

**Section 1** includes a Reconciliation of a Non-GAAP Performance Measure for each non-GAAP metric included in the release to which this supplemental information is attached, except for the reconciliation pertaining to Adjusted Net Income for the second quarter of 2009, which is included in the body of the release to which this supplemental information is attached.

**Section 2** contains explanations of each of the specified items listed in each Reconciliation of a Non-GAAP Performance Measure included in Section 1 of this Supplemental Information Schedule or in the text of the press release to which the schedule is attached.

Section 3 provides detailed disclosures indicating the reasons management believes our non-GAAP measures are useful.

# Section 1

# Consolidated EBITDA Orthofix International NV

(In thousands)

	Q2 2009	TTM 6/30/09
Orthofix:		
Net Income/(loss)	\$ 5,944	\$ (229,144)
Depreciation and Amortization	5,397	25,309
Interest	5,881	22,445
Unrealized non-cash loss (gain) on interest rate swap	(1,037)	6,699
Allowable loss on refinancing of senior secured term loar	n -	3,660
Tax Expense	3,331	(67,069)
123R expense	2,507	11,262
Product Commercialization Investments	2,100	11,000
Impairment charge	-	289,523
Other Non-Cash Charges	(584)	3,403
Consolidated EBITDA	\$23,539	\$ 77,088

NOTE: For the definition of Consolidated EBITDA please refer to a copy of the credit agreement, dated September 22, 2006, which was filed as Exhibit 10.1 to Orthofix's current report on Form 8-K filed on September 27, 2006, and a copy of the first amendment to the credit agreement, dated September 29, 2008, which was filed as Exhibit 10.1 to Orthofix's current report on Form 8-K filed on September 29, 2008. These documents can be found at the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>.

#### Section 2

# Description of Second Quarter 2009 Specified Items (earnings reconciliation)

- Unrealized, non-cash gain on interest rate swap- resulted from changes in the fair value of the Company's interest rate swap. Mark-to-market adjustments are required to be reported in quarterly earnings through the expiration of the swap in June 2011.
- Strategic investments- costs related to the Company's strategic investment in the development and commercialization of a new stem cell-based allograft with MTF.
- Foreign exchange (gain)/loss- due to unrealized, non-cash translation adjustments resulting from a strengthening or weakening of the U.S. dollar against various foreign currencies. A number of Orthofix's foreign subsidiaries have intercompany and trade accounts payable that are held in currencies, most notably the U.S. Dollar, other than their local currency, and movements in the relative values of those currencies result in foreign exchange gains and losses.
- Reorganization/consolidation costs- costs associated with reorganization and facility consolidation plans within various areas of the Company, primarily related to the spinal implants division.

# **Net Income to Consolidated EBITDA**

- Depreciation and Amortization- non-cash depreciation and amortization expenses
- Interest- interest expense related to outstanding debt.
- Unrealized non-cash loss (gain) on interest rate swap- from changes in the fair value of the Company's interest rate swap. Mark-to-market adjustments are required to be reported in quarterly earnings through the expiration of the swap in June 2011.
- Allowable loss on refinancing of senior secured term loan- costs associated with the completion of an amended credit facility in the 3<sup>rd</sup> guarter of 2008.
- Tax expense- non-cash tax expenses
- 123R expense- non-cashequity compensation expenses
- **Product commercialization investments-** costs associated with the Development and Commercialization Agreements with MTF, and the acquisition and development of IP from IIS.
- Impairment charge- anon-cash impairment charge taken in Q408 related to the value of certain intangible assets
- Other non-cash charges- certainnon-cash charges including foreign exchange losses, an inventory step up related to an acquisition and the amortization of a prepaid royalty.

## Section 3

# Management use of, and economic substance behind, Non-GAAP Performance Measures

Management uses non-GAAP measures, referred to as "adjusted net income" and "Consolidated EBITDA" (earnings before interest, taxes, depreciation and amortization) to evaluate performance period over period, to analyze the underlying trends in the Company's business, to assess its performance relative to its competitors, and to establish operational goals and forecasts that are used in allocating resources. In

addition, following the Company's acquisition of Blackstone, and the related increase in Orthofix's debt, management has increased its focus on cash generation and debt reduction. Management uses these non-GAAP measures as the basis for assessing the ability of the underlying operations to generate cash for use in paying down debt. In addition, management uses these non-GAAP measures to further its understanding of the performance of the Company's business segments. The items excluded from Orthofix's non-GAAP measures are also excluded from the profit or loss reported by the Company's business segments for the purpose of analyzing their performance.

### Material Limitations Associated with the Use of Non-GAAP Measures

The non-GAAP measures used in this release may have limitations as analytical tools, and should not be considered in isolation or as a replacement for GAAP performance measures. Some of the limitations associated with the use of these non-GAAP performance measures are that they exclude items that reflect an economic cost to the Company and can have a material effect on cash flows. Similarly, equity compensation expense does not directly impact cash flows, but is part of total compensation costs accounted for under GAAP.

# Compensation for Limitations Associated with Use of Non-GAAP Measures

Orthofix compensates for the limitations of its non-GAAP performance measures by relying upon its GAAP results to gain a complete picture of the Company's performance. The GAAP results provide the ability to understand the Company's performance based on a defined set of criteria. The non-GAAP measures reflect the underlying operating results of the Company's businesses, excluding non-cash items, which management believes is an important measure of the Company's overall performance.

The Company provides a detailed reconciliation of the non-GAAP performance measures to their most directly comparable GAAP measures, and encourages investors to review this reconciliation.

### **Usefulness of Non-GAAP Measures to Investors**

Orthofix believes that providing non-GAAP measures that exclude certain items provides investors with greater transparency to the information used by the Company's senior management in its financial and operational decision-making. Management believes that providing this information enables investors to better understand the performance of the Company's ongoing operations and to understand the methodology used by management to evaluate and measure such performance. Disclosure of these non-GAAP performance measures also facilitates comparisons of Orthofix's underlying operating performance with other companies in its industry that also supplement their GAAP results with non-GAAP performance measures.

SOURCE: Orthofix International N.V.

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