



July 26, 2012

## Orthofix International Announces 2nd Quarter 2012 Results

**Net Sales were \$119.5 million, up 2%; 5% constant currency; Reported and Adjusted Net Income from continuing operations up 33% and 11%, respectively**

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V. (NASDAQ:OFIX) (the Company) today announced its results for the second quarter ended June 30, 2012. Net sales of \$119.5 million represent an increase of 2% over the second quarter of last year. Net sales grew 5% on a constant currency basis. Net income from continuing operations was \$14.0 million, or \$0.73 per diluted share compared to net income from continuing operations of \$10.5 million, or \$0.57 per diluted share, in the prior year. Adjusted net income was up 11% to \$14.9 million, or \$0.78 per diluted share compared to \$13.4 million, or \$0.72 per diluted share, in the prior year.

"The second quarter results demonstrate the strength of our Regenerative Solutions and highlights our strategy to leverage our differentiated product offerings across both our Spine and Orthopedic business units," commented President and Chief Executive Officer Robert Vaters. "In addition, the close of the Sports Medicine divestiture provides us with the financial capacity and flexibility to make the necessary investments to drive long-term growth."

### Sales Performance

Net sales were \$119.5 million in the second quarter of 2012, up 2% on a reported basis, and 5% on a constant currency basis, from \$116.7 million in the second quarter of the prior year. Foreign currency negatively impacted second quarter net sales by approximately \$3.3 million, or 3% of net sales.

### External net sales by global business unit

	Three Months Ended June 30,			
	2012	2011	Reported Growth	Constant Currency Growth
<i>(USD in millions)</i>				
<b>Spine</b>				
Spine Repair Implants and Regenerative Biologics	\$ 38.5	\$ 36.9	4%	4%
Spine Regenerative Stimulation	43.3	39.7	9%	9%
<b>Total Spine</b>	81.8	76.5	7%	7%
<b>Orthopedics</b>	37.7	40.1	-6%	2%
<b>Total net sales</b>	<u>\$ 119.5</u>	<u>\$ 116.7</u>	<u>2%</u>	<u>5%</u>

Note: Some calculations may be impacted by rounding.

Second quarter net sales for the Company's Spine global business unit were up 7% to \$81.8 million, which was driven by a 9% increase in Regenerative Stimulation products used in spine applications. Revenue from Repair Implants and Regenerative Biologics increased 4% over prior year, which was primarily a result of increased adoption of Trinity® Evolution™ in spine applications, which led to a 48% increase in sales of Regenerative Biologics in the second quarter of 2012.

For the Company's Orthopedic global business unit, second quarter net sales were \$37.7 million, decreasing 6% on a reported basis, while increasing 2% on a constant currency basis, compared to the prior year. Foreign currency negatively impacted reported net sales by \$3.3 million, or 9% of net orthopedic sales. Constant currency sales growth was driven by sales of Regenerative Biologics in Orthopedic applications, along with recently launched internal fixation systems for the foot and ankle.

### Earnings Performance

Reported net income from continuing operations for the second quarter of 2012 was \$14 million and net income from continuing operations per diluted share was \$0.73. Excluding certain items summarized in the table below, adjusted net income in the second quarter of 2012 was \$14.9 million, or \$0.78 per diluted share, increasing 11% and 8%, respectively from the second quarter of the prior year.

The following table reconciles reported net income and net income per diluted share to adjusted net income and adjusted net income per diluted share for each of the quarters ended June 30, 2012 and 2011:

<b>Second Quarter Adjusted Net Income from Continuing operations</b>	<b>Q2 2012</b>		<b>Q2 2011</b>		<b>% Change</b>	
	<b>(\$000's)</b>	<b>EPS</b>	<b>(\$000's)</b>	<b>EPS</b>	<b>(\$000's)</b>	<b>EPS</b>
Reported GAAP net income from continuing operations	\$ 13,967	\$ 0.73	\$ 10,519	\$ 0.57	33%	28%
<i>Specified Items:</i>						
Arbitration Resolution of Co-Development Agreement	1,953					
Charges related to U.S. Government resolutions	859		-			
Foreign exchange gain/loss	(518)		153			
Change in Estimate of Tax Deduction	(1,332)					
Succession and Restructuring Charges			2,738			
Adjusted Net Income from continuing operations	<u>\$ 14,929</u>	<u>\$ 0.78</u>	<u>\$ 13,410</u>	<u>\$ 0.72</u>	<u>11%</u>	<u>8%</u>
Shares used to calculate EPS (in thousands)		19,216		18,541		

Note: Some calculations may be impacted by rounding. Please refer to the Non-GAAP Performance Measure section at the end of this press release for more information about the specified items listed above.

The following table reconciles operating income to adjusted operating income for each of the quarters ended June 30, 2012 and 2011:

<b>Second Quarter Adjusted Operating Income</b>	<b>Q2 2012</b>		<b>Q2 2011</b>	
	<b>(\$000's)</b>	<b>% of Sales</b>	<b>(\$000's)</b>	<b>% of Sales</b>
Reported GAAP operating income	\$ 20,565	17.2%	\$ 19,396	16.6%
<i>Specified Items:</i>				
Arbitration Resolution of Co-Development Agreement	3,100		-	
Charges related to U.S. Government resolutions	1,364		-	
Succession and Restructuring Charges	-		3,505	
Adjusted operating income	<u>\$ 25,029</u>	<u>20.9%</u>	<u>\$ 22,901</u>	<u>19.6%</u>

Note: Some calculations may be impacted by rounding. Please refer to the Non-GAAP Performance measure section at the end of this press release for more information about the specified items listed above.

After adjusting for a \$3.1 million charge in R&D for an unfavorable arbitration resolution related to a 2008 co-development agreement, and the \$1.4 million charges for prejudgment interest related to U.S. Government resolutions, the second quarter 2012 adjusted operating margin increased 130 basis points to 20.9% over the same period of the prior year. This increase was primarily the result of leverage from SG&A expenses on higher sales.

The second quarter for 2012 also included \$0.4 million (\$0.3 million, net of tax) or \$0.01 per diluted share of legal expenses associated with the closing of the Department of Justice (DOJ) investigation of the bone growth stimulation business and the

Company's Foreign Corrupt Practices Act (FCPA) matter at the Company's former orthopedic distribution entity in Mexico, each of which were finalized during the second quarter with the signing and filing of definitive settlement agreements. The prior year reported and adjusted results included \$1.6 million (\$1.0 million net of tax) or \$0.05 per diluted share of legal expenses associated with the DOJ and FCPA matters mentioned above.

## 2012 Outlook Update

Based upon changes in foreign currency exchange rates, the Company expects net sales from continuing operations to be between \$481 million to \$491 million for the full year 2012 or a 2% to 4% increase over the corresponding net sales from continuing operations in 2011. The Company expects GAAP earnings per share from continuing operations to be approximately \$2.79 to \$2.89 per diluted share, and adjusted earnings per share from continuing operations to be approximately \$2.95 to \$3.05 per diluted share.

The following tables update the 2012 full year guidance for the change in foreign currency estimates and updated specified items.

### Net Sales from Continuing Operations- Full Year 2012

*in millions*

Previous Guidance Range	\$487-\$497
Incremental Foreign Exchange	(\$6)
Revised Guidance Range	<u>\$481-\$491</u>

### Reported and Adjusted EPS from Continuing Operations - Full Year 2012

Reported GAAP EPS from Continuing Operations Range	\$ 2.79 - \$ 2.89
--	-------------------

#### Specified Items:

Strategic Investment MTF	\$0.10
Arbitration Resolution of Co-Development Agreement	\$0.10
Charges related to U.S. Government resolutions	\$0.04
Change in Estimate of Tax Deduction	(\$0.07)
Foreign exchange loss (income)	(\$0.01)
Adjusted EPS from Continuing Operations Range	<u>\$ 2.95 - \$ 3.05</u>

## 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 of 2012. Interested parties may access the conference call by dialing (888) 267-2845 in the U.S. and (973) 413-6102 outside the U.S., and entering the conference ID 38220. A replay of the call will be available for two weeks by dialing (800) 332-6854 in the U.S. and (973) 528-0005 outside the U.S., and entering the conference ID 38220. A webcast of the conference call may be accessed by going to the Company's website at [www.orthofix.com](http://www.orthofix.com), clicking on the Investors link and then the Events and Presentations page.

## About Orthofix

Orthofix International N.V. is a diversified, global medical device company focused on developing and delivering innovative repair and regenerative solutions to the spine and orthopedic markets. Orthofix's products are widely distributed around the

world to orthopedic surgeons and patients via Orthofix's sales representatives and its subsidiaries, and via collaborations with other leading orthopedic product companies. In addition, Orthofix is collaborating on R&D activities with leading research and clinical organizations such as the Musculoskeletal Transplant Foundation, the Orthopedic Research and Education Foundation, and Texas Scottish Rite Hospital for Children. For more information about Orthofix, please visit [www.orthofix.com](http://www.orthofix.com).

### **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.

The forward-looking statements in this release do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to the expected sales of our products, including recently launched products, unanticipated expenditures, the resolution of pending litigation matters (including the government investigation and False Claims Act matter relating to our spinal implant business, as well as our indemnification obligations with respect to certain retained product liability claims against, and the government investigation of our former Sports Medicine global business unit) and our ongoing compliance obligations under a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services and a deferred prosecution agreement with the U.S. Department of Justice, changing relationships with customers, suppliers, strategic partners and lenders, changes to and the interpretation of governmental regulations, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry, credit markets and the economy, corporate development and market development activities, including acquisitions or divestitures, unexpected costs or operating unit performance related to recent acquisitions, and other factors described in our annual report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed by the Company with the Securities and Exchange Commission (SEC). Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update or revise the information contained in this press release (which contains information current as of the date hereof, whether as a result of new information, future events or circumstances, or otherwise).

The Company cannot predict the timing or outcome of ongoing litigation matters and governmental investigations of our businesses which could result in civil or criminal liability or findings of violations of law (as further described in the "Legal Proceedings" sections of our annual report on Form 10-K and quarterly reports on Form 10-Q), that could materially impact our financial position and/or liquidity.

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Net sales	\$ 119,492	\$ 116,670	\$ 235,534	\$ 229,731
Cost of sales	23,676	23,186	45,616	45,527
Gross profit	95,816	93,484	189,918	184,204
Operating expenses				
Sales and marketing	49,810	49,960	99,331	97,399
General and administrative	14,295	17,344	28,865	36,130
Research and development	9,252	6,229	16,302	11,673
Amortization of intangible assets	530	555	1,060	1,103
Charges related to U.S. Government resolutions	1,364	-	1,364	46,000
	75,251	74,088	146,922	192,305
Operating income (loss)	20,565	19,396	42,996	(8,101)
Other income and expense				

Interest expense, net	(1,265)	(2,198)	(3,486)	(4,613)
Other income (expense), net	660	(342)	29	(1,451)
	<u>19,960</u>	<u>16,856</u>	<u>39,539</u>	<u>(14,165)</u>
Income (loss) before income taxes				
Income tax expense	(5,993)	(6,337)	(13,356)	(12,056)
Net income (loss) from continuing operations, net of tax	<u>13,967</u>	<u>10,519</u>	<u>26,183</u>	<u>(26,221)</u>
Discontinued operations				
Gain on sale of Breg, Inc. net of tax	1,040	-	1,040	-
Income (loss) from discontinued operations	(5,846)	(796)	(6,352)	676
Income tax (expense) benefit	2,044	235	2,350	(298)
Net income (loss) from discontinued operations, net of tax	<u>(2,762)</u>	<u>(561)</u>	<u>(2,962)</u>	<u>378</u>
Net income (loss)	<u>\$ 11,205</u>	<u>\$ 9,958</u>	<u>\$ 23,221</u>	<u>(\$25,843)</u>
Net income (loss) per common share - basic				
Net income (loss) from continuing operations, net of tax	\$ 0.74	\$ 0.58	\$ 1.40	(\$1.45)
Net income (loss) from discontinued operations, net of tax	(\$0.15)	(\$0.03)	(\$0.16)	\$ 0.02
Net income (loss) per common share - basic	<u>\$ 0.59</u>	<u>\$ 0.55</u>	<u>\$ 1.24</u>	<u>(\$1.43)</u>
Net income (loss) per common share - diluted				
Net income (loss) from continuing operations, net of tax	\$ 0.73	\$ 0.57	\$ 1.37	(\$1.45)
Net income (loss) from discontinued operations, net of tax	(\$0.15)	(\$0.03)	(\$0.16)	\$ 0.02
Net income (loss) per common share - diluted	<u>\$ 0.58</u>	<u>\$ 0.54</u>	<u>\$ 1.21</u>	<u>(\$1.43)</u>
Weighted average number of common shares outstanding - basic	18,827,452	18,110,607	18,751,573	18,024,913
Weighted average number of common shares outstanding - diluted	19,215,984	18,541,220	19,168,940	18,024,913
Comprehensive Income (Loss)	\$ 6,822	\$ 11,793	\$ 21,548	(\$20,918)

Note: Some calculations may be impacted by rounding

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

	<u>June 30,</u>	<u>December 31,</u>
	<u>2012</u>	<u>2011</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 50,089	\$ 33,207
Restricted cash	72,913	45,476
Trade accounts receivable, net	149,472	132,828
Inventories, net	78,423	82,969
Deferred income taxes	20,106	16,349
Escrow receivable	-	41,537
Prepaid expenses and other current assets	25,386	26,069
Assets held for sale	-	171,185
Total current assets	<u>396,389</u>	<u>549,620</u>
Property, plant and equipment, net	45,267	43,368

Patents and other intangible assets, net	7,294	8,236
Goodwill	73,111	73,094
Deferred income taxes	18,444	18,584
Other long-term assets	12,815	11,570
Total assets	<u>\$553,320</u>	<u>\$ 704,472</u>

#### Liabilities and shareholders' equity

##### Current liabilities:

Bank borrowings	\$ 499	\$ 1,318
Current portion of long-term debt	-	17,500
Trade accounts payable	11,551	16,488
Accrued charges related to U.S. Government resolutions	83,864	82,500
Other current liabilities	50,132	45,327
Liabilities held for sale	-	22,676
Total current liabilities	<u>146,046</u>	<u>185,809</u>

Long-term debt	40,000	191,195
Deferred income taxes	9,781	9,778
Other long-term liabilities	3,277	2,519
Total liabilities	<u>199,104</u>	<u>389,301</u>

##### Shareholders' equity:

Common shares	1,895	1,846
Additional paid-in capital	231,758	214,310
Retained earnings	120,475	97,254
Accumulated other comprehensive income	88	1,761
Total shareholders' equity	<u>354,216</u>	<u>315,171</u>

Total liabilities and shareholders' equity	<u>\$553,320</u>	<u>\$ 704,472</u>
--	------------------	-------------------

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

	Six Months Ended June 30,	
	2012	2011
Cash flows from operating activities:		
Net income (loss)	\$ 23,221	(\$25,843)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	11,018	11,324
Other non-cash adjustments	626	7,952
Change in operating assets and liabilities:		
Escrow receivable	41,537	(326)
Charges related to U.S. Government resolutions	1,364	46,000
Changes in working capital	(20,010)	(15,704)
Net cash provided by operating activities	<u>57,756</u>	<u>23,403</u>
Cash flows from investing activities:		
Capital expenditures	(13,008)	(11,298)
Payment made in connection with acquisition	-	(5,250)
Net proceeds from sale of Breg, Inc.	153,092	-
Net cash provided by (used in) investing activities	<u>140,084</u>	<u>(16,548)</u>

Cash flows from financing activities:

Net proceeds from issuance of common shares	13,341	13,453
Repayments of long-term debt	(168,695)	(2,500)
Payment of refinancing fees	-	(758)
Repayment of bank borrowings, net	(831)	(1,653)
Change in restricted cash	(25,831)	(2,285)
Cash payment for purchase of minority interest in subsidiary	-	(517)
Tax benefit on non-qualified stock options	1,156	1,004
Net cash (used in) provided by financing activities	<u>(180,860)</u>	<u>6,744</u>
Effect of exchange rate changes on cash	<u>(98)</u>	<u>325</u>
Net increase in cash and cash equivalents	16,882	13,924
Cash and cash equivalents at the beginning of period	33,207	13,561
Cash and cash equivalents at the end of period	<u>\$ 50,089</u>	<u>\$ 27,485</u>

## Non-GAAP Performance Measures

The tables in this press release present reconciliations of net sales, net income (loss) and net income (loss) per diluted share, operating income and effective tax rate calculated in accordance with generally accepted accounting principles (GAAP) to non-GAAP performance measures, referred to as "Adjusted Constant Currency Net Sales", "Adjusted Net Income and Adjusted Net Income per Diluted Share", "Adjusted EPS from Continuing Operations" and "Adjusted Operating Income" that exclude the items specified in the tables. 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 tables below that are excluded from GAAP net sales and GAAP net income (loss) and net income (loss) per diluted share, 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.

## Reconciliations of Non-GAAP Performance Measures

### Adjusted Net Income from continuing operations and Adjusted Net Income from continuing operations per Diluted Share Reconciling Items

Note: The reconciling items were tax effected in the current period at the prevailing rate within the respective jurisdictions.

- **Arbitration Resolution of Co-Development Agreement** — costs related to finalizing a 2008 co-development agreement.
- **Charges related to U.S. Government resolutions** —prejudgment interest associated with: finalizing definitive agreements to resolve the U.S. Government investigation of the Company's bone growth stimulation business, including resolution of a related civil matter; and finalizing definitive agreements to resolve the U.S. Government investigation of Blackstone Medical, Inc., including resolution of a related civil matter
- **Foreign exchange loss (income)** — due to translation adjustments resulting from the weakening or strengthening of the U.S. Dollar against various foreign currencies. A number of Orthofix's foreign subsidiaries have intercompany and third party trade accounts receivables and payables 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.
- **Change in Estimate of Tax Deduction** —change in the estimate of the tax deduction associated with the settlement of the U.S. Government investigation of the Company's bone growth stimulation business.
- **Succession and Restructuring Charges** — In 2011, these costs relate to the cessation of employment of the Company's Chief Executive Officer and certain other employees.

### Adjusted Operating Income Reconciling Items

- **Arbitration Resolution of Co-Development Agreement** — costs related to finalizing a 2008 co-development agreement.
- **Charges related to U.S. Government resolutions** —prejudgment interest associated with: finalizing definitive agreements to resolve the U.S. Government investigation of the Company's bone growth stimulation business, including resolution of a related civil matter; and finalizing definitive agreements to resolve the U.S. Government investigation of Blackstone Medical, Inc., including resolution of a related civil matter.

- **Succession and Restructuring Charges** — In 2011, these costs relate to the cessation of employment of the Company's Chief Executive Officer and certain other employees.

### **Adjusted EPS from Continuing Operations Reconciling Items**

Note: The reconciling items were tax effected in the current period at the prevailing rate within the respective jurisdictions.

- **Strategic Investment MTF** — costs related to the Company's strategic investment with MTF in the development and commercialization of the next generation cell based bone growth technology.
- **Arbitration Resolution of Co-Development Agreement** — costs related to finalizing a 2008 co-development agreement.
- **Charges related to U.S. Government resolutions** —prejudgment interest associated with: finalizing definitive agreements to resolve the U.S. Government investigation of the Company's bone growth stimulation business, including resolution of a related civil matter; and finalizing definitive agreements to resolve the U.S. Government investigation of Blackstone Medical, Inc., including resolution of a related civil matter.
- **Change in Estimate of Tax Deduction** —change in the estimate of the tax deduction associated with the settlement of the U.S. Government investigation of the Company's bone growth stimulation business.
- **Foreign exchange loss (income)** — due to translation adjustments resulting from the weakening or strengthening of the U.S. Dollar against various foreign currencies. A number of Orthofix's foreign subsidiaries have intercompany and third party trade accounts receivables and payables 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.

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

Management uses non-GAAP measures 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 recent years, 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 units. The items excluded from Orthofix's non-GAAP measures are also excluded from the profit or loss reported by the Company's business units for the purpose of analyzing their performance.

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

The non-GAAP measures used in this press 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.



Orthofix International N.V.  
Mark Quick, 214-937-2924  
Director of Investor Relations and Business Development  
[markquick@orthofix.com](mailto:markquick@orthofix.com)

Source: Orthofix International N.V.

News Provided by Acquire Media