

ORTHOFIX INTERNATIONAL N V
Form 8-K
July 28, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 28, 2005

Orthofix International N.V.

(Exact name of Registrant as specified in its charter)

Netherlands Antilles
(State or other jurisdiction
of incorporation)

0-19961
Commission File
Number

N/A
(I.R.S. Employer
Identification Number)

7 Abraham de Veerstraat
Curacao
Netherlands Antilles
(Address of principal executive
offices)

N/A
(Zip Code)

Registrant's telephone number, including area code: 011-59-99-465-8525

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition

On July 28, 2005, Orthofix International N.V. issued a press release announcing, among other things, its results of operations for the second quarter and six months ended June 30, 2005. A copy of the press release is furnished herewith as Exhibit 99.1 and attached hereto.

Item 9.01. Financial Statements and Exhibits

(c) Exhibits

99.1 Press release of Orthofix International N.V. dated July 28, 2005.

SIGNATURE

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 hereunto duly authorized.

ORTHOFIX INTERNATIONAL, N.V.

BY: /s/ THOMAS HEIN

Name: Thomas Hein
Title: Chief Financial Officer

Date: July 28, 2005

For Further Information:

Charles W. Federico
Group President & CEO
Orthofix International N.V.
704.948.2600

Thomas Hein
CFO
Orthofix International N.V.
704.948.2600

Orthofix Reports Record Quarterly Sales of \$79.5 Million for the Second Quarter 2005

**2nd Quarter Net Income Increases 19% to \$9.4 million,
or \$0.58 per Diluted Share**

HUNTERSVILLE, N.C., July 28, 2005 Orthofix International N.V. (NASDAQ:OFIX) today announced results for the second quarter and six months ended June 30, 2005.

Sales for the second quarter ended June 30, 2005, were \$79.5 million, an increase of 12% over the \$70.8 million reported during the same period in 2004. The incremental impact of foreign currency on sales for the second quarter of 2005 was a positive \$0.9 million or 1.1%.

Net income for the second quarter ended June 30, 2005, was \$9.4 million, or \$0.58 per diluted share, an increase of 19%, compared with \$7.9 million, or \$0.50 per diluted share, for the same period in 2004. Diluted weighted average shares outstanding were 16,294,098 and 15,872,346 during the three months ended June 30, 2005, and June 30, 2004, respectively.

For the six months ended June 30, 2005, sales were \$157.2 million, an increase of 11% over the \$141.5 million reported during the same period in 2004. The incremental impact of foreign currency on sales for the first six months of 2005 was a positive \$1.9 million or 1.2%.

Net income for the six months ended June 30, 2005, was \$20.2 million, or \$1.24 per diluted share, an increase of 24%, compared with \$16.2 million, or \$1.02 per diluted share, for the same period in 2004. Diluted weighted average shares outstanding were 16,228,849 and 15,826,981 during the six months ended June 30, 2005, and June 30, 2004, respectively.

The following tables display net sales by business segment, net of inter-company eliminations and by market sector for the three and six months ended June 30, 2005, and 2004. We provide net sales by market sector for information purposes only. We maintain our books and records by business segment.

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Net sales by business segment for the periods ended June 30,
(In millions)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	2004	% Increase	2005	2004	% Increase
Americas Orthofix	\$ 35.9	\$ 31.1	15%	\$ 69.6	\$ 60.9	14%
Americas Breg	17.4	16.4	6%	35.4	33.3	6%
International Orthofix	26.2	23.3	12%	52.2	47.3	10%
Total	\$ 79.5	\$ 70.8	12%	\$ 157.2	\$ 141.5	11%

Net sales by market sector for the periods ended June 30,
(In millions)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	2004	% Increase	2005	2004	% Increase
Orthopedic Products						
Spine	\$ 25.2	\$ 20.3	24%	\$ 48.4	\$ 39.9	21%
Reconstruction	31.7	29.2	9%	64.3	59.3	8%
Trauma	16.6	16.1	3%	32.6	31.4	4%
Total Orthopedic	73.5	65.6	12%	145.3	130.6	11%
Non-Orthopedic	6.0	5.2	15%	11.9	10.9	9%
Total	\$ 79.5	\$ 70.8	12%	\$ 157.2	\$ 141.5	11%

Charles W. Federico, President and CEO of Orthofix, stated, "We are pleased to be able to report record second quarter sales of \$79.5 million led by strong year-over-year sales growth in our Spine market sector. The growth in both the second quarter and year-to-date periods is being driven by market acceptance of Cervical-Stim®. As we expected, the Cervical-Stim® has cannibalized some stimulation sales previously recorded in the Trauma market sector. A comparison of stimulation sales, used across all applications, reflects a strong 20% and 18% growth for the second quarter and year-to-date periods versus the prior year. These strong growth rates can only indicate market share gain."

Further, additional gains were recognized due to the introduction of the Guided-Growth Plate (eight-Plate) that is used in pediatric deformity corrections," added Federico. "Early indications lead us to believe this product will be a meaningful contributor to the ongoing growth of the Reconstruction market sector. The ISKD Internal Lengthener, with an increase of 79% over the same period of the prior year, also contributed to the year-to-date growth of the Reconstruction market sector."

The growth of our Breg products has been affected by a delay in introducing new products for bracing and cold therapy applications," continued Federico. "We have recently introduced the Polar Care® 500 Lite and the Fusion XT knee brace, both of which we believe will support positive gains in sales of Breg products."

Although our Trauma market sector was affected, as discussed above, it is important to note that we continue to see above 30% growth in our PC.C.P product over the same periods in 2004," Federico added. "The continued market acceptance of the PC.C.P along with the introduction of the Distal Radius Plate (Contours VPS) and our entry into biologics (OsteoMax Bone Void Filler) should provide us with the platform to accelerate the growth rate in the Trauma market sector."

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Federico stated further, "On 12% sales growth for the second quarter, operating income grew 26%. This leverage was principally the result of an excellent 73.9% gross profit margin in the quarter reflecting a favorable spinal stimulation product mix."

The Company noted that, because a higher proportion of its pre-tax income was earned in the United States, its effective tax rate had increased to 36% for the quarter and 35% year-to-date. The Company further stated that, because of a recently enacted Finance Bill in the United Kingdom which will increase its taxes in the United Kingdom, it expects its effective tax rate to increase further over the remainder of the year.

The Company made further scheduled and voluntary prepayments totaling \$8.0 million on its outstanding term loan during the quarter, reducing the balance on the term loan used to finance the Breg acquisition from an initial balance of \$110.0 million to \$60.8 million at June 30, 2005.

Orthofix International, N.V., a global diversified orthopedic products company, offers a broad line of minimally invasive surgical, as well as non-surgical, products for the spine, reconstruction, and trauma 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 via partnerships with other leading orthopedic product companies, such as Medtronic Sofamor Danek and Kendall Healthcare. In addition, Orthofix is collaborating in R&D partnerships with leading medical institutions such as the Orthopedic Research and Education Foundation, the Cleveland Clinic Foundation, Innovative Spinal Technologies and National Osteoporosis Institute. For more information about Orthofix, please visit 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, 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 integration of the businesses of Orthofix and Breg, unanticipated expenditures, changing relationship with customers, suppliers and strategic partners, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, changes to 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 and other factors described in the most recent report on Form 10-K and other periodic reports filed by Orthofix with the Securities and Exchange Commission.

- Financial tables follow -

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

	For the three months		For the six months	
	ended June 30,		ended June 30,	
	2005	2004	2005	2004
Net sales	\$ 79,540	\$ 70,794	\$ 157,228	\$ 141,533
Cost of sales	20,775	19,697	41,671	39,243
Gross profit	58,765	51,097	115,557	102,290
Operating expenses				
Sales and marketing	28,799	25,638	56,397	51,774
General and administrative	8,703	7,418	17,379	14,667
Research and development	2,869	2,694	5,808	6,010
Amortization	1,661	1,813	3,289	3,145
KCI litigation costs	163	332	505	704

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	For the three months		For the six months	
	42,195	37,895	83,378	76,300
Operating income	16,570	13,202	32,179	25,990
Interest expense, net	(1,251)	(1,370)	(2,561)	(2,899)
Other income/(loss), net	(608)	(173)	1,435	17
Gain/(loss) in joint venture	-	(180)	-	225
Income before income tax	14,711	11,479	31,053	23,333
Income tax expense	(5,306)	(3,604)	(10,869)	(7,114)
Net income	\$ 9,405	\$ 7,875	\$ 20,184	\$ 16,219
Net income per common share - basic	\$ 0.59	\$ 0.52	\$ 1.28	\$ 1.07
Net income per common share - diluted	\$ 0.58	\$ 0.50	\$ 1.24	\$ 1.02
Weighted average number of common shares outstanding - basic	15,872,638	15,276,961	15,828,686	15,158,409
Weighted average number of common shares outstanding - diluted	16,294,098	15,872,346	16,228,849	15,826,981

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

	As of	As of
	June 30,	December 31,
	2005	2004
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,145	\$ 25,944
Restricted cash	9,571	14,302
Trade accounts receivable	82,215	75,321
Inventory	33,234	32,895
Deferred income taxes	3,948	4,130
Prepaid expenses and other	12,391	10,000
Total current assets	161,504	162,592
Securities and other investments	4,082	4,082
Property, plant and equipment, net	19,041	18,326
Intangible assets, net	234,549	239,956
Other long-term assets	5,205	6,144
Total assets	\$424,381	\$431,100

Liabilities and shareholders' equity
Current liabilities:

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	As of	As of
Bank borrowings	\$ 69	\$ 76
Current portion of long-term debt	10,302	10,057
Trade accounts payable	9,748	9,507
Other current liabilities	20,408	25,745
Total current liabilities	40,527	45,385
Long-term debt	50,917	67,249
Deferred income taxes	16,812	17,555
Deferred income		2,443
Other long-term liabilities	1,270	1,296
Total liabilities	109,526	133,928
Shareholders' equity		
Common shares	1,593	1,572
Additional paid-in capital	103,787	98,388
Retained earnings	105,380	99,960
Accumulated other comprehensive income	202,257	182,073
	7,218	15,139
Total shareholders' equity	314,855	297,172
Total liabilities and shareholders' equity	\$424,381	\$431,100

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

	For the six months ended June 30	
	2005	2004
Net cash provided by (used in) operating activities	\$ 13,073	\$ (18)
Cash flows from investing activities:		
Investment in subsidiaries and affiliates		(2,081)
Capital expenditure	(6,101)	(7,758)
Proceeds from sale of investments		1,300
Proceeds from sale of assets		1,578
Other		440
Net cash used in investing activities	(6,101)	(6,521)
Cash flows from financing activities:		
Net repayment of loans and borrowings	(16,094)	(3,705)
Proceeds from issuance of common stock	3,964	7,135
Payment of debt issuance costs		(529)
Net cash (used in) provided by financing activities	(12,130)	2,901

	For the six months ended June 30	
Effect of exchange rate changes on cash	(641)	(117)
Net decrease in cash and cash equivalents	(5,799)	(3,755)
Cash and cash equivalents at the beginning of the period	25,944	31,356
Cash and cash equivalents at the end of the period	\$ 20,145	\$ 27,601