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))

Item 2.02. <u>Results of Operations and Financial Condition</u>

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.

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

	Three Months Ended June 30,			Si	x Months	nths Ended June 30,				
	2005	5	2004	1	% Increase	200)5	200)4	% Increase
Americas Orthofix Americas Breg International Orthofix	\$	35.9 17.4 26.2	\$	31.1 16.4 23.3	15% 6% 12%	\$	69.6 35.4 52.2	\$	60.9 33.3 47.3	14% 6% 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 Mon	ths Ended June 30,	Six Months Ended June 30,			
	2005	2004 % Increase	2005	% 2004 Increase		
Orthopedic Products Spine Reconstruction Trauma	\$ 25.2 31.7 16.6	\$ 20.3 24% 29.2 9% 16.1 3%	\$ 48.4 64.3 32.6	\$ 39.9 21% 59.3 8% 31.4 4%		
Total Orthopedic Non-Orthopedic	73.5 6.0	65.612%5.215%	145.3 11.9	130.6 11% 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-Platethat 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.

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 <u>www.orthofix.com</u>.

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 Ju	ıne 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		

	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 Other income/(loss), net Gain/(loss) in joint venture		(1,251) (608)		(1,370) (173) (180)		(2,561) 1,435		(2,899) 17 225
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 Net income per common share - diluted	\$ \$	0.59 0.58	\$ \$	0.52 0.50	\$ \$	1.28 1.24	\$ \$	1.07 1.02
Weighted average number of common shares outstanding - basic	15	5,872,638	15	5,276,961	15	5,828,686	1:	5,158,409
Weighted average number of common shares outstanding - diluted	16	5,294,098	15	5,872,346	16	5,228,849	1:	5,826,981

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:

\$ 69 10,302 9,748 20,408	\$ 76 10,057 9,507
9,748	· · · · · · · · · · · · · · · · · · ·
	9 507
20,408),507
	25,745
40,527	45,385
50,917	67,249
16,812	17,555
	2,443
1,270	1,296
109,526	133,928
1,593	1,572
103,787	98,388
105 380	99,960
	182,073
7,218	15,139
314,855	297,172
\$424,381	\$431,100
	40,527 50,917 16,812 1,270 109,526 1,593 103,787 105,380 202,257 7,218 314,855

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

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

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