

ORTHOFIX INTERNATIONAL N V
Form 10-K
March 16, 2007

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 10-K

× ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

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
(State or other jurisdiction of incorporation or
organization)

N/A

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

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

N/A
(Zip Code)

599-9-4658525
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$0.10 par value
(Title of Class)

Nasdaq Global Select Market
(Name of Exchange on Which Registered)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes T No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No T

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 at least the past 90 days.

Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Large Accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of registrant's common stock held by non-affiliates, based upon the closing price of the common stock on the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2006, as reported by the Nasdaq National Market, was approximately \$611.2 million. Shares of common stock held by executive officers and directors and persons who own 5% or more of the outstanding common stock have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not a determination for any other purpose.

As of March 13, 2007, 16,472,443 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's Proxy Statement to be filed with the Commission in connection with the 2007 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Form 10-K.

1

Table of Contents

		<u>Page</u>
<u>PART I</u>		4
	Item 1. <u>Business</u>	4
	Item 1A. <u>Risk Factors</u>	23
	Item 1B. <u>Unresolved Staff Comments</u>	32
	Item 2. <u>Properties</u>	33
	Item 3. <u>Legal Proceedings</u>	34
	Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	34
<u>PART II</u>		35
	Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	35
	Item 6. <u>Selected Financial Data</u>	38
	Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	39
	Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	51
	Item 8. <u>Financial Statements and Supplementary Data</u>	52
	Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	52
	Item 9A. <u>Controls and Procedures</u>	52
	Item 9B. <u>Other Information</u>	52
<u>Part III</u>		53
	Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	53
	Item 11. <u>Executive Compensation</u>	57
	Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	57
	Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	57
	Item 14. <u>Principal Accountant Fees and Services</u>	57
<u>Part IV</u>		58
	Item 15. <u>Exhibits and Financial Statement Schedules</u>	58

Table of Contents

Forward-Looking Statements

This Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, relating to our business and financial outlook, 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,” “projects,” “predicts,” “potential” or “continue” or other comparable terminology. These forward-looking statements are not guarantees 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, or the risk factors described in Item IA under the heading “Risk Factors,” 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, unanticipated expenditures, changing relationships with customers, suppliers and strategic partners, unfavorable results in litigation matters, 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, currency or interest rate fluctuations and the other risks described under Item 1A – “Business – Risk Factors” in this Form 10-K.

Table of Contents

PART I

Item 1. Business

In this Form 10-K, the terms “we”, “us”, “our”, “Orthofix” and “our Company” refer to the combined operations of all of Orthofix International N.V. and its respective consolidated subsidiaries and affiliates, unless the context requires otherwise.

OVERVIEW

We are a diversified orthopedic products company offering a broad line of surgical and non-surgical products principally in 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 biologics; non-invasive 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, other pain management products, bone cement and devices for removal of bone cement used to fix artificial implants and airway management products used in anesthesia applications.

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.

Orthofix International N.V. is a limited liability company, organized under the laws of the Netherlands Antilles on October 19, 1987. Our principal executive offices are located at 7 Abraham de Veerstraat, Curaçao, Netherlands Antilles, telephone number: 599-9-465-8525. Our filings with the Securities and Exchange Commission, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, annual proxy statement on Schedule 14A and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the Securities and Exchange Commission. Information on our website or connected to our website is not incorporated by reference into this Form 10-K. Our Internet website is located at <http://www.orthofix.com>. Our SEC filings are also available on the SEC Internet website as part of the EDGAR database (<http://www.sec.gov>).

Table of Contents

Important Events

On December 11, 2006, we announced that Chief Executive Officer Alan W. Milinazzo had been appointed to the Company's Board of Directors, to fill the vacancy on the Board of Directors left by the retirement of Mr. Robert Gaines-Cooper, one of Orthofix's founders and the Chairman of the Board from 1989 to 2004. Mr. Milinazzo does not currently serve on any committees of the Board of Directors. Mr. Gaines-Cooper, retired as director of Orthofix International N.V. on December 5, 2006.

On September 22, 2006, we completed the acquisition of privately held Blackstone Medical, Inc. ("Blackstone"), a company specializing in the design, development and marketing of spinal implant and related biologics products. The purchase price for the acquisition was \$333.0 million, subject to certain closing adjustments, plus transaction costs totaling approximately \$9.2 million as of December 31, 2006. Financing costs were approximately \$6.0 million. The acquisition and related costs were financed with \$330.0 million of senior secured bank debt and cash on hand. The Company's results, for the year ended December 31, 2006, include the results of Blackstone from the date of acquisition along with the impact of purchase accounting and interest expense associated with the acquisition.

On February 16, 2006, we announced that Alan W. Milinazzo, 47, the Company's then Chief Operating Officer, had been promoted to Group President and Chief Executive Officer effective April 1, 2006. Mr. Milinazzo succeeded Charles W. Federico, who remains a Director of Orthofix. Mr. Milinazzo joined the Company on September 6, 2005, in a newly established position of Chief Operating Officer, from Medtronic Inc. where he was Vice President of Medtronic's Vascular business, as well as Vice President and General Manager of Medtronic's Coronary and Peripheral business.

On September 30, 2005, we announced that we had reached an agreement to settle the patent litigation between our subsidiary Novamedix Distribution, Ltd. and Kinetic Concepts, Inc. ("KCI") related to our A-V Impulse System®. Under the terms of the settlement, KCI agreed to pay Novamedix \$75 million, and we received a limited assignment of certain KCI foot pump patent rights. KCI retains rights in the patents and will maintain its Plexi Pulse foot pump product line going forward. The settlement resolves and settles all claims between the parties. In the first quarter of 2006, we distributed approximately \$22.9 million of the settlement proceeds to certain parties including former owners of Novamedix, pursuant to contracts requiring those disbursements.

Business Strategy

Our business strategy is to offer innovative, cost-effective orthopedic products to the Spine, Orthopedic, Sports Medicine and Vascular market sectors that reduce both patient suffering and healthcare costs. We intend to continue to expand applications for our products by utilizing synergies among our core technologies. We intend to expand our product offerings through business or product acquisition and assignment or licensing agreements, as well as through our own product development efforts. We will leverage our sales and distribution network by selling our products in all markets in which we can generate adequate financial returns. We intend to continue to enhance physician relationships through extensive education efforts as well as strengthen contracting and reimbursement relationships through our dedicated sales and administrative staff.

Table of Contents**Business Segments and Market Sectors**

Our business is divided into four reportable segments: Orthofix Domestic (“Domestic”), Blackstone, Breg, and Orthofix International (“International”). Domestic consists of operations of our subsidiary Orthofix Inc. that 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. We have designated Blackstone, our newly acquired subsidiary, as a business segment. Blackstone specializes in the design, development and marketing of spinal implant and related biologic products. Blackstone uses distributor sales representatives to sell Spine products domestically and internationally. Breg designs, manufactures, and distributes orthopedic products for post-operative reconstruction and rehabilitative patient use and sells those Sports Medicine products through a network of domestic and international distributors, sales representatives, and affiliates. International consists of locations in Europe, Mexico, Brazil, and Puerto Rico, as well as independent distributors outside the United States. International uses both direct and distributor sales representatives to sell Spine, Orthopedic, Sports Medicine, Vascular, and Other products.

Business Segment (a):

	Year ended December 31, (In US\$ thousands)					
	2006		2005		2004	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	\$ 152,560	42%	\$ 135,084	43%	\$ 118,074	41%
Blackstone	28,134	8%	-	-	-	-
Breg	76,219	21%	72,022	23%	68,294	24%
International	108,446	29%	106,198	34%	100,270	35%
Total	\$ 365,359	100%	\$ 313,304	100%	\$ 286,638	100%

(a) Prior to 2006 our operations in Mexico and Brazil were included within the Orthofix Domestic segment.

Conversely, in 2006 such operations are included within Orthofix International. The prior year presentation has been restated to conform with the current presentation.

Additional financial information regarding our business segments can be found in Part II, Item 8, “Financial Statements and Supplementary Data”, as well as in Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

We maintain our books and records by business segment; however, we use market sectors to describe our business. 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. Market sectors, which categorize our revenues by types of products, describe the net sales of our Company more clearly than our business segments.

Our market sectors, which were reformatted in 2006 to more clearly associate our products with markets, are Spine, Orthopedics, Sports Medicine, Vascular, and Other.

Table of Contents

Market Sector:

	Year ended December 31, (In US\$ thousands)				
	2006		2005		2004
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales
Spine	\$ 145,113	40%	\$ 101,622	33	