ORTHOFIX INTERNATIONAL N V
Form 10-K
March 03, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2010

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)

Curaçao	**N/A**
(State or other jurisdiction of	**(I.R.S. Employer**

incorporation or organization)	Identification No.)
7 Abraham de Veerstraat	
Curaçao	**N/A**
(Address of principal executive offices)	**(Zip Code)**

599-9-4658525

(Registrant s telephone number, including area code)

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

Common Stock, $0.10 par value	**Nasdaq Global Select Market**
(Title of Class)	**(Name of Exchange on Which Registered)**

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

None

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

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 x

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 the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated filer ¨	Accelerated filer x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

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, 2010, as reported by the Nasdaq Global Select Market, was approximately $556.6 million.

As of February 28, 2011, 18,024,295 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant s Definitive Proxy Statement to be filed with the Commission in connection with the 2011 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Form 10-K.

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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, anticipat believes, estimates, projects, intends, predicts, potential or continue or other comparable terminology. These forward-looking statemen 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 1A under the heading Risk Factors, to reflect new information, the occurrence of future events or circumstances or otherwise.

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, changing relationships with customers, suppliers, strategic partners and lenders, changes to and the interpretation of governmental regulations, ongoing 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 section of this Form 10-K), 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 risks described in Item 1A under the heading Risk Factors in this Form 10-K.

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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.

Company Overview

We are a diversified orthopedic products company offering a broad line of surgical and non-surgical products for the Spine, Orthopedics, Sports Medicine and Other Products 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 human cellular and tissue based products (HCT/P products), non-invasive bone growth 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 cold therapy and bone cement and devices for removal of bone cement used to fix artificial implants.

We have administrative and training facilities in the United States (U.S.) and Italy and manufacturing facilities in the U.S., the United Kingdom, Italy and Mexico. We directly distribute our products in the U.S., the United Kingdom, Italy, Germany, Switzerland, Austria, France, Belgium, Brazil and Puerto Rico. In several other markets we distribute our products through independent distributors.

Orthofix International N.V. is a limited liability company operating under the laws of Curacao. The company was formed on October 19, 1987 under the laws of the Netherlands Antilles, with the principal offices on the island of Curacao. Curacao became a separate and autonomous country on October 10, 2010. Our principal executive offices are located at 7 Abraham de Veerstraat, Curaçao, telephone number: 599-9-465-8525. Our filings with the Securities and Exchange Commission (the SEC), 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 SEC. 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 IDEA database (http://www.sec.gov).

2010 and 2011 Business Highlights

Business Highlights

Key Management Changes In January 2011, we promoted Robert S. Vaters to the position of Chief Operating Officer responsible for the day-to-day activities of our three global business units. Mr. Vaters was our Chief Financial Officer from September 2008 until this promotion. Mr. Vaters also serves as President of our Spine Global Business unit. Also, In March 2011, we promoted Brian McCollum to the position of Chief Financial Officer and Senior Vice President of Finance. Beginning January 1, 2011, we began managing our business by our three global business units of Spine, Orthopedics and Sports Medicine.

New Credit Agreement In August 2010, we entered into a Credit Agreement (the New Credit Agreement) with certain domestic direct and indirect subsidiaries of the Company (the Guarantors), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto. The

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New Credit Agreement is comprised of a $100 million secured term loan facility (the Term Loan Facility) and a $200 million secured revolving credit facility (the Revolving Credit Facility, and together with the Term Loan Facility, the Credit Facilities). We used these borrowings to repay all amounts owed under a Senior Secured Bank Credit Facility (2006 Credit Facility) that we entered into in connection with our acquisition of Blackstone in September 2006. We terminated the 2006 Credit Facility in August 2010. The New Credit Agreement requires us to comply with leverage and fixed charge coverage ratios and contains affirmative and negative covenants. We have the ability to increase the amount of the Credit Facilities by an aggregate amount of up to $50.0 million upon satisfaction of certain conditions. These increased borrowings may be provided either by one or more existing lenders upon us obtaining the agreement of such lenders to increase commitments or by new lenders being added to the Credit Facilities.

Consolidation and Reorganization of Businesses We have announced several initiatives to consolidate and reorganize our current businesses into global business units as well as relocate our executive offices to our new facility in Lewisville, TX. During 2010, we closed certain facilities in the U.S. and Mexico and we subleased our facility in Boston, MA. Beginning in 2011, our reportable segments will be our three global business units of Spine, Orthopedics and Sports Medicine along with corporate activities.

Divestures and Exit Activities We completed the sale of our vascular product line in March 2010 for gross proceeds of $27.7 million. The net cash proceeds of $19.0 million from the sale were used to pay down borrowings on our credit facility in advance of the scheduled maturity date. In addition, in June 2010, we terminated a distribution arrangement for anesthesia products we distributed in the United Kingdom.

Deleveraging the Balance Sheet We continue to focus on reducing the balance on our credit facility. In 2010, we made principal payments of approximately $36.3 million, of which $19.0 million related to the divesture of our vascular business. The outstanding credit facility balance was $216.2 million and $252.4 million at December 31, 2010 and 2009, respectively. Our leverage ratio, as defined in the credit facility, was 2.1 at December 31, 2010, compared to 2.6 at December 31, 2009.

Business Strategy

Our business strategy is to offer innovative products to the Spine, Orthopedics and Sports Medicine market sectors that reduce both patient suffering leading to a more active and mobile lifestyle and healthcare costs. Our strategy for growth and profitability includes the following initiatives by market sector:

Spine: Provide a portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of spinal conditions. Our main tactics and objectives are:

- Increase revenues with market penetration of spine stimulation;
- Continue new product introductions of spinal implants and biologics with a focus on building a strong foundation of competitive core fusion products to ensure that our product portfolio addresses all aspects of spinal fusion therapy including degenerative disc disease, deformity and tumor/trauma market segments;
- Improve gross margins on spinal implants and biologic products with the efficient use of research and development resources, increasing operating leverage with original equipment manufacturer (OEM) vendors, and the continued increase of Trinity® Evolution; and
- Decrease sales and marketing and general and administrative expenses with the previously mentioned consolidation and reorganization plans.

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Orthopedics: Provide a portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of orthopedic conditions ranging from trauma to deformity correction. Our main tactics and objectives are:

- Continue new and next generation product introductions;
- Maintain focus on sales of external fixation, internal fixation along with deformity correction devices by expanding sales into the U.S., Latin America, Europe, and Asia;
- Optimize product offerings within each of our geographic markets;
- Focus on sales of long-bone stimulation and biologics in the U.S.;
- Continue the introduction of Trinity® Evolution; and
- Decrease sales and marketing and general and administrative expenses with the previously mentioned consolidation and reorganization plans.

Sports Medicine: Provide a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Our main tactics and objectives are:

- Optimize distribution channels;
- Leverage strong market share in high growth areas such as Osteoarthritis knee bracing and cold therapy; and
- Launch innovative products and expand service solutions into new and existing market segments.

Other Financial and Business Initiatives:

- Improve operating margins across all business units as a result of the consolidation and reorganization initiatives;
- Continue to expand applications for our products by utilizing synergies among our core technologies;
- Continue to enhance physician relationships through extensive product education and training programs; and
- Continue to strengthen contracting, reimbursement relationships and billing capabilities.

Business Segments and Market Sectors

Through 2010, we have divided our business into four reportable segments: Domestic, Spinal Implants and Biologics, Breg, and International. Domestic consists of operations of our subsidiary Orthofix Inc., which uses both direct and distributor sales representatives to sell Spine and Orthopedic products to hospitals, doctors, and other healthcare providers in the U.S. market. Spinal Implants and Biologics consists of Blackstone Medical, Inc., and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Spinal Implants and Biologics specializes in the design, development and marketing of spinal implant and related HCT/P products. Spinal Implants and Biologics distributes its products through a network of domestic and international distributors, sales representatives and affiliates. 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 U.S. International uses both direct and distributor sales representatives to sell Spine, Orthopedics, Sports Medicine and Other Products to hospitals, doctors and other healthcare providers.

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Business Segments:

	Year ended December 31, (US$ in thousands)					
	2010		2009		2008	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	$ 228,221	41%	$ 210,703	38%	$ 188,807	36%
Spinal Implants and Biologics	130,523	23%	118,680	22%	108,966	21%
Breg	91,664	16%	92,188	17%	89,478	17%
International	113,962	20%	124,064	23%	132,424	26%
Total	$ 564,370	100%	$ 545,635	100%	$ 519,675	100%

Additional financial information regarding our business segments can be found in Item 7 under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations , as well as in Item 8 under the heading Financial Statements and Supplementary Data .

We maintain our books and records by business segment; however, we use market sectors to describe our business. Our segment information is prepared on the same basis that our management reviews the financial information for operational decision making purposes. Market sectors, which categorize our revenues by types of products, describe the nature of our business more clearly than our business segments.

Our market sectors are Spine, Orthopedics, Sports Medicine and Other Products.

Market Sectors:

	Year ended December 31, (US$ in thousands)					
	2010		2009		2008	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Spine	$ 306,422	54%	$ 279,425	51%	$ 252,239	49%
Orthopedics	144,448	26%	131,310	24%	129,106	25%
Sports Medicine	95,462	17%	96,366	18%	94,528	18%
Other Products	18,038	3%	38,534	7%	43,802	8%
Total	$ 564,370	100%	$ 545,635	100%	$ 519,675	100%

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

Products

Our revenues are generally derived from the sales of products in three market sectors, Spine (54%), Orthopedics (26%) and Sports Medicine (17%), which collectively accounted for 97% of our total net sales in 2010. Sales of our Other Products, which included vascular, airway management products for use during anesthesia, woman s care and other products, accounted for 3% of our total net sales in 2010.

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The following table identifies our principal products by trade name and describes their primary applications:

Product	Primary Application
Spine Products	
Cervical-Stim®	Pulsed electromagnetic field (PEMF) non-invasive cervical spine bone growth stimulator
Spinal-Stim®	PEMF non-invasive lumbar spine bone growth stimulator
Alloquent® Allografts	Interbody devices made of cortical bone that are designed to restore the space that has been lost between two or more vertebrae due to a degenerated disc
Trinity® Evolution	An adult stem cell-based bone growth matrix used during surgery that is designed to enhance the success of a spinal fusion procedure
3 Degree/Reliant Anterior Cervical Plating Systems	Plating systems implanted during anterior cervical spine fusion procedures
Hallmark® Anterior Cervical Plate System	A cervical plating system implanted during anterior cervical spine fusion procedures
Ascent® LE Posterior Occipital Cervico-Thoracic (POCT) System	A system of pedicle screws and rods implanted during a posterior spinal fusion procedure involving the stabilization of several degenerated or deformed cervical vertebrae
NewBridge® Laminoplasty Fixation System	A device implanted during a posterior surgical procedure designed to expand the cervical vertebrae and relieve pressure on the spinal canal
Construx® Mini Polyetheretherketones (PEEK) Vertebral Body Replacement (VBR) System	Smaller, unibody versions of the Construx PEEK VBR System, implanted during the replacement of degenerated or deformed spinal vertebrae
Construx® PEEK VBR System	A modular device implanted during the replacement of degenerated or deformed spinal vertebrae to provide additional anterior support
NGage® Surgical Mesh System	A modular metallic interbody implant placed between two vertebrae designed to restore disc space and increase stability that has been lost due to degeneration or deformity
PILLAR PL & TL PEEK VBR System	Interbody devices for Posterior Lumbar Interbody Fusion (PLIF) and Trans-laminar Lumbar Interbody Fusion (TLIF) procedures
PILLAR AL PEEK Partial VBR System	An intervertebral body fusion device for Anterior Lumbar Interbody Fusion (ALIF) procedures
PILLAR SA PEEK Spacer System	An intervertebral body fusion device that incorporates screw fixation to optimize implant stability
Firebird Spinal Fixation System	A system of rods, crossbars and modular pedicle screws designed to be implanted during a posterior lumbar spine fusion procedure
ProView Minimal Access Portal (MAP) System	An instrument system for minimally invasive posterior lumbar spinal fusion, including tubular and expandable retractors, a percutaneous screw delivery system and the ONYX System for Disc removal and interbody space preparation
Unity® Lumbosacral Fixation System	A plating system implanted during anterior lumbar spine fusion procedures

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Product	Primary Application
Orthopedic Products	
Fixation	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus®, XCaliber, Contours VPS®, VeroNail® and Gotfried PC.C.P®
Physio-Stim®	PEMF long bone non-invasive bone growth stimulator
Trinity® Evolution	An adult stem cell-based bone growth matrix used during surgery to facilitate bone fusion
Origen DBM with Bioactive Glass	A bone void filler
Eight-Plate Guided Growth System®	Treatment for bowed legs or knock knees of children
ISKD®	Internal limb-lengthening device
Limb Reconstruction System (LRS) and LRS ADVanced	External fixation for lengthenings and corrections of deformity
TrueLok	Ring fixation system for limb lengthening and deformity correction
PREFIX and PREFIX 2	External fixation range for temporary fixation of fractures in trauma
Centronail® Titanium Nailing System	Complete range of intramedullary nails including the Humeral Nail
Cemex®	Bone cement
OSCAR	Ultrasonic bone cement removal
Sports Medicine Products	
Breg® Bracing	Bracing products which are designed to provide support and protection of limbs, extremities and back during healing and rehabilitation
Polar Care® and KODIAK®	Cold therapy products that are designed to reduce swelling, pain and accelerate the rehabilitation process
OrthoSelect services and Vision Inventory Management System	Consulting services which provide guidance and tools to improve overall practice efficiency and a web based inventory system customized to enable efficient management of orthopedic devices

We have proprietary rights in all of the above products with the exception of Cemex®, ISKD®, Eight-Plate Guided Growth System® and Contour VPS®. We have the exclusive distribution rights for the Cemex® in Italy and for the ISKD®, Eight-Plate Guided Growth System® and Contour VPS® worldwide.

We have numerous trademarked products and services including but not limited to the following: Orthofix®, Blackstone®, Breg®, Spinal-Stim®, Cervical-Stim®, Origen DBM, 3 Degree, Reliant, Hallmark®, Firebird, Ascent®, Construx®, Unity®, NGage®, Newbridge®, Trinity® Evolution, PILLAR, Alloquent®, ProView, ProCallus®, XCaliber, VeroNail®, Centronail®, PREFIX, Gotfried PC.C.P®, Physio-Stim®, TrueLok, Polar Care® and Fusion®.

Spine

Spine product sales represented 54% of our total net sales in 2010.

Neck and back pain is a common health problem for many people throughout the world and often requires surgical or non-surgical intervention for improvement. Neck and back problems are usually of a degenerative nature and are generally more prevalent among the older population. As the population ages, we believe physicians will see an increasing number of patients with degenerative spine issues who wish to have a better