

ORTHOFIX INTERNATIONAL N V  
Form 8-K  
June 07, 2012

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

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**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): **June 6, 2012**

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**Orthofix International N.V.**

(Exact name of Registrant as specified in its charter)

**Curaçao**

(State or other jurisdiction of incorporation)

**0-19961**

(Commission File Number)

**N/A**

(IRS Employer Identification No.)

**7 Abraham de Veerstraat**

**Curaçao**

(Address of principal executive offices)

**N/A**

(Zip Code)

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

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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 1.01. Entry into a Material Definitive Agreement.**

*Settlement and Plea Agreements Regarding Regenerative Bone Growth Stimulation Business Matter*

On June 6, 2012, Orthofix International N.V. (the Company ) entered into a settlement agreement (the BGS Settlement Agreement ) with the United States of America, acting through the United States Department of Justice (the DOJ ) and on behalf of the Office of Inspector General of the Department of Health and Human Services (the OIG-HHS ), the TRICARE Management Activity, through its General Counsel, the Office of Personnel Management, in its capacity as administrator of the Federal Employees Health Benefits Program, the United States Department of Veteran Affairs and relator Jeffrey J. Bierman. The BGS Settlement Agreement finally resolves (i) the previously disclosed government investigation surrounding the HIPAA subpoenas issued by the United States Attorney's Office for the District of Massachusetts (the Boston USAO ) on April 10, 2009, July 23, 2009 and June 3, 2010, respectively, and (ii) the previously disclosed qui tam complaint filed by Jeffrey J. Bierman in the U.S. District Court for the District of Massachusetts against the Company and Orthofix Inc.

In connection with the BGS Settlement Agreement, the Company's wholly-owned subsidiary, Orthofix Inc., entered into a plea agreement with the Boston USAO and the DOJ (the Plea Agreement ) on June 7, 2012 under which Orthofix Inc. will plead guilty to one felony count of obstruction of a federal audit (§18 U.S.C. 1516). The Plea Agreement is subject to approval by the United States District Court for the District of Massachusetts.

Under the BGS Settlement Agreement, the Company will pay \$34,234,263 (plus interest at a rate of 3% from May 5, 2011 through the day before payment is made). Under the Plea Agreement, Orthofix Inc. will pay (i) a criminal fine of \$7,765,737, and (ii) a mandatory special assessment of \$400. The Company previously recorded a charge of \$43 million during the first quarter of 2011 in anticipation of the settlement and related fees owed to counsel for Mr. Bierman.

*Corporate Integrity Agreement with the OIG-HHS*

In connection with each of the foregoing agreements, and in anticipation of a final settlement of the previously disclosed government investigation and related qui tam complaint involving the Company's subsidiary Blackstone Medical, Inc., the Company also entered into a five-year corporate integrity agreement with the OIG-HHS on June 6, 2012 (the CIA ). The CIA acknowledges the existence of the Company's current compliance program, and requires that the Company continue to maintain during the term of the CIA a compliance program designed to promote compliance with federal health care and Food and Drug Administration ( FDA ) requirements. The Company is also required to maintain several elements of the existing program during the term of the CIA, including maintaining a Chief Compliance Officer, a Compliance Committee, and a Code of Conduct. The CIA requires that the Company conduct certain additional compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations. Pursuant to the CIA, the Company is required to notify the OIG-HHS in writing, among other things, of: (i) any ongoing government investigation or legal proceeding involving an allegation that the Company has committed a crime or has engaged in fraudulent activities; (ii) any other matter that a reasonable person would consider a probable violation of applicable criminal, civil, or administrative laws related to compliance with Federal healthcare programs or FDA requirements; and (iii) any change in location, sale, closing, purchase, or establishment of a new business unit or location related to items or services that may be reimbursed by Federal health care programs. The Company is also subject to periodic reporting and certification requirements attesting that the provisions of the CIA are being implemented and followed, as well as certain document and record retention mandates.



The settlement is neither an admission of liability by the Company or its subsidiaries nor a concession by the United States or the civil qui tam relator that their claims are not well founded, except as to such admissions as Orthofix, Inc. makes in connection with its guilty plea under the Plea Agreement.

Participation in Federal healthcare programs by the Company, which was not prosecuted, will not be affected by the settlement. In the event of an uncured material breach of the CIA, the Company could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

The foregoing descriptions of the BGS Settlement Agreement, the Plea Agreement and the CIA do not purport to be complete and are qualified in their entirety by the text of those agreements, which will be filed with an amendment to this Current Report on Form 8-K as Exhibits 10.1, 10.2 and 10.3 thereto, respectively.

*This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, 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, intends, 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. Such risks and uncertainties include the impact of the Company's settlements of the federal investigations described in this Form 8-K, including the Company's compliance with the CIA through June 2017, and those risks and uncertainties discussed in the Company's filings with the Securities and Exchange Commission (including those described in Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2011, under the heading, Risk Factors and the Company's subsequently filed reports pursuant to the Securities and Exchange Act of 1934. 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 to reflect new information, the occurrence of future events or circumstances or otherwise.*

**SIGNATURES**

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/ Brian McCollum*  
Brian McCollum  
Senior Vice President of Finance and Chief Financial  
Officer

Date: June 7, 2012