

# Orthofix International Moves to Resolve U.S. Government Legal Matters

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V., (NASDAQ:OFIX) (the Company) announced today that it has made significant progress in resolving several outstanding legal matters with the U.S. Government. These highlights include:

- Reaching an agreement in principle to resolve the U.S. Government investigation of Blackstone Medical, Inc.
- Reaching an agreement in principle with the U.S. Department of Justice to settle violations of the Foreign Corrupt Practices Act.
- Finalizing definitive agreements to resolve criminal and civil matters related to the U.S. Government investigation of its bone growth stimulation business.

"I am very pleased with the substantial progress made regarding these three legal matters, which removes a significant amount of risk and uncertainty for the Company," said President and Chief Executive Officer Robert Vaters. "Orthofix has made significant improvements to its compliance practices, personnel, and financial standing to provide a strong foundation from which to grow. I look forward to a stronger focus on the Company's operations, including investments in R&D to position the Company for long-term growth, while maintaining earnings improvement."

#### Agreement in Principle Reached for Blackstone Medical, Inc.

The Company has reached an agreement in principle with the U.S. Attorney's Office for the District of Massachusetts to pay \$32 million to resolve matters related to the investigation of the Company's subsidiary, Blackstone Medical, Inc. ("Blackstone"). The settlement will be funded by proceeds received by the Company from the escrow fund established in connection with the agreement and plan of merger between the Company and Blackstone in 2006 and includes resolution of a qui tam complaint filed by Susan Hutcheson against Blackstone and the Company in the U.S. District Court for the District of Massachusetts. In addition, the Company resolved remaining escrow claims with the former equity holders of Blackstone. As a result of the settlement, the Company will receive approximately \$9 million in cash and take a charge of approximately \$6.0 million during the fourth quarter 2011 for previously incurred legal fees. The final settlement is subject to the negotiation and approval of definitive agreements with the U.S. Attorney's Office, the U.S. Department of Justice ("DOJ"), and the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG").

#### Agreement in Principle Reached with the DOJ for Foreign Corrupt Practices Act Matter

The Company also reached an agreement in principle with the DOJ to settle criminal violations of the Foreign Corrupt Practices Act (FCPA) that it voluntarily reported to the U.S. Government in June 2010 concerning its former Mexican orthopedic distribution entity. In the first quarter 2011 financial results, the Company reported that it had recorded a charge of \$3.0 million to establish an accrual in connection with this matter based on the results of its own internal investigation and an analysis of similar FCPA resolutions. As the result of recent discussions with the DOJ and staff at the U.S. Securities and Exchange Commission, the Company plans to take a charge of approximately \$4.5 million in the fourth quarter 2011 to establish as an additional accrual in anticipation of a proposed criminal and civil resolution of this matter. Final resolution is subject to the negotiation and execution of definitive agreements with the DOJ.

## <u>Finalizing Definitive Agreements for Bone Growth Stimulation Matters</u>

The Company is also finalizing definitive agreements with the U.S. Attorney's Office, the DOJ, and the OIG to resolve criminal and civil matters related to an investigation of its bone growth stimulation business, which includes resolution of a qui tam lawsuit pending in the U.S. District Court for the District of Massachusetts. Under the terms of the agreements, the Company will pay the U.S. Government \$43 million, a charge previously disclosed and already accrued by the Company in the first quarter 2011. Orthofix Inc., a subsidiary of the Company, expects to plead to a violation of 18 USC 1516, related to an obstruction of a June 2008 federal audit. The Company and Orthofix Inc. also expect to enter into a five-year Corporate Integrity Agreement (CIA) with the OIG as part of the resolution of these matters.

In summary, as a result of the matters described above, the Company expects a pre-tax impact of approximately \$10.5 million to its fourth quarter 2011 financial results and expects to receive cash of approximately \$9 million from the Blackstone escrow fund. The Company had previously obtained an amendment to its current credit facility to provide additional capacity under the various restrictive covenants for these charges by the Company.

### **About Orthofix:**

Orthofix International N.V. is a diversified, global medical device company focused on developing and delivering innovative repair and regenerative solutions to the spine and orthopedic markets. 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 collaborations with other leading orthopedic product companies. In addition, Orthofix is collaborating on R&D activities with leading research and clinical organizations such as the Musculoskeletal Transplant Foundation, the Orthopedic Research and Education Foundation, Texas Scottish Rite Hospital for Children, and the Cleveland Clinical Foundation. For more information about Orthofix, please visit <a href="https://www.orthofix.com">www.orthofix.com</a>.

## **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 and its subsidiaries and 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.

The forward-looking statements in this release do not constitute guarantees or promises of future performance. 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, the resolution of pending litigation matters (including the government investigation and False Claims Act matters relating to our bone growth stimulation and spinal implant businesses, and the possible violations of the FCPA by our former Mexican orthopedic distribution entity, as well as certain product liability claims against our sports medicine global business unit), changing relationships with customers, suppliers, strategic partners and lenders, changes to and the interpretation of governmental regulations, 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 factors described in our annual report on Form 10-K and other periodic reports filed by the Company with the Securities and Exchange Commission (SEC). Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances, or otherwise.

The Company cannot predict the timing or outcome of ongoing litigation matters and 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" sections of our annual report on Form 10-K and quarterly reports on Form 10-Q), that could materially impact our financial position and/or liquidity.

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