

Orthofix Announces Exclusive US License for IGEA's Bone and Joint Stimulation Devices

4/28/2021

Orthofix to pursue FDA approval of IGEA's solutions to expand the Company's US Bone Growth Therapy offerings

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and extremities focus, today announced they have entered into an exclusive license agreement to commercialize the innovative portfolio of Italy-based **IGEA S.p.A's** bone, cartilage and soft tissue stimulation products in the U.S and Canada.

Under terms of this agreement, Orthofix has the rights to pursue U.S Food and Drug Administration approvals and commercialization of IGEA's platform of orthopedic products, which are not currently available in the U.S. These products, which will be marketed under the Orthofix brand, will expand Orthofix's bone growth therapies portfolio of Pulsed Electromagnetic Field (PEMF) products with additional treatment modalities and indications such as Low-Intensity Pulsed Ultrasound (LIPUS) and Capacitive Coupling (CC) for fracture management. The license also includes innovative, new technology applications designed to address joint inflammation, pain, and cartilage protection.

"Orthofix is the U.S. market leader with our PEMF technology bone growth stimulation systems indicated for post-operative spinal fusions and treating bone fractures that have not healed after surgery, and IGEA is the European market and technology leader for bone and joint stimulation," said Orthofix President and Chief Executive Officer Jon Serbousek. "Combined, these portfolios will enable us to offer physicians and patients additional treatment solutions for fracture management and complement our pursuit of new indications for managing soft tissue and joint health such as our ongoing rotator cuff repair IDE clinical study."

Founded 40 years ago at the University of Modena, Italy, IGEA is a leader in the manufacturing and distribution of bone and joint cartilage stimulation systems which include stimulation modalities of LIPUS, PEMF and capacitive coupling. Outside of the U.S. more than 20,000 patients are treated every year with their products.

“As a company with a long history of treating patients in Europe, we are excited to enter into this agreement that will expand the availability of our bone and joint cartilage systems to patients in the U.S.,” said IGEA President, and founder Dr. Ruggero Cadossi. “Aligning with Orthofix’s expertise and distribution in the stimulation market enables us to provide even more physicians access to our innovative products to improve patient outcomes.”

About Orthofix

Orthofix Medical Inc. is a global medical device and biologics company with a spine and orthopedics focus. The Company’s mission is to deliver innovative, quality-driven solutions as we partner with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, Orthofix’s spine and orthopedics products are distributed in more than 70 countries via the Company’s sales representatives and distributors. For more information, please visit www.Orthofix.com.

About IGEA

IGEA is committed to research in the area of clinical biophysics developing innovative medical devices for therapeutic purposes. IGEA focuses on orthopedic applications for bone and cartilage healing and oncologic applications for drug and gene electrotransfer. IGEA products are distributed in all European countries through distributors or its subsidiaries. For more information, please visit www.igeamedical.com.

Forward Looking Statements

This communication 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, including the risks described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2020 (the “2020 Form 10-K”). In addition to the risks described there, factors that could cause or contribute to such differences may include, but are not limited to: the risk that FDA approvals may be delayed or not be obtained; the risk that surgeons may be slow to adopt the IGEA orthopedic products; the risk that future patient studies or clinical experience and data may indicate that treatment with the IGEA orthopedic products does not improve patient outcomes as much as previously believed, or otherwise call into question the benefits of its use to patients, hospitals and surgeons; the risk that the product may not perform as intended and may therefore not achieve commercial success; the risk that competitors may develop superior products or may have a greater market position enabling more successful commercialization; the risk that insurance payers may decline to reimburse healthcare providers for the use of our products.

This list of risks, uncertainties and other factors is not complete. We discuss some of these matters more fully, as well as certain risk factors that could affect our business, financial condition, results of operations, and prospects, in

reports we file from time-to-time with the SEC, which are available to read at www.sec.gov. Any or all forward-looking statements that we make may turn out to be wrong (due to inaccurate assumptions that we make or otherwise), and 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 hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to update, and expressly disclaim any duty to update, our forward-looking statements, whether as a result of circumstances or events that arise after the date hereof, new information, or otherwise.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20210428005245/en/>

Alexa Huerta

Investor Relations

Tel 214 937 3190

alexahuerta@orthofix.com

Denise Landry

Media Relations

Tel 214 937 2529

deniselandry@orthofix.com

Source: Orthofix Medical Inc.