



OSSIO Receives FDA 510(k) Clearance for OSSIOfiber™ Bone Pin Product Family

New Bio-Integrative Orthopedic Fixation Material Provides Unprecedented Combination of Mechanical Strength and Natural Bone Healing in a Non-Permanent Implant

WOBURN, MA. – January 14, 2019 – OSSIO, an orthopedic fixation company, today announced that its OSSIOfiber™ Bone Pin Family has received 510(k) market clearance from the U.S. Food and Drug Administration (FDA). This first of its kind technology features a proprietary bio-integrative material to provide stability and secure bone fixation during the healing process, leaving no permanent hardware behind. While the OSSIOfiber™ platform will have broad application across the spectrum of orthopedics, its first commercial use will be in the foot and ankle segment for the treatment of forefoot conditions where hardware removal surgeries are prevalent.

The OSSIOfiber™ Bone Pin Family comprises the company's breakthrough OSSIOfiber™ Intelligent Bone Regeneration Technology, a new category of non-permanent fixation material that aims to be the first credible replacement to permanent fixation implants. Made from a proprietary natural mineral fiber matrix, its bio-integrative material properties provide surgeons with a more biologically friendly way to restore patient stability and mobility while leaving nothing permanent behind.

“OSSIO has a revolutionary new platform that will change the way we think about orthopedic fixation for both bone and soft tissue,” said [Bob Baravarian, DPM](#), Assistant Clinical Professor, UCLA School of Medicine, and Director, University Foot and Ankle Institute, Santa Monica, CA. “Surgical procedures to treat forefoot conditions are increasing in frequency as the population ages. While these procedures are considered to be effective, they can be associated with secondary implant removal surgeries due to mechanical failure, irritation and pain. OSSIOfiber™ has the potential to be a true game-changer, with pre-clinical studies demonstrating its mechanical strength and bio-integrative nature.”

At the time of surgery, OSSIOfiber™ provides ease of insertion and secure fixation without requiring any changes to surgeons' existing techniques. Initially, the mechanical strength of the novel implant is significantly higher than cortical bone, and its performance supports bone regeneration throughout the healing process. It then gradually transfers load to the native bone following the critical rehabilitation phase. Unlike metal, the stiffness of OSSIOfiber™ is a better mechanical match to bone and this improved bone compliance can prevent stress risers and weakening of the bone around the implant. As confirmed in pre-clinical studies, full integration into the surrounding anatomy takes place within approximately 18-24 months, leaving only native bone behind with no residual hardware.

Metal implants represent the current standard of care in orthopedic fixation; however, permanent hardware creates a sub-optimal healing environment, which can lead to patient dissatisfaction and increasing healthcare costs due to post-operative complications and secondary removal surgeries. Over the course of the last few decades, there have been numerous attempts to develop fixation implants from various bio-resorbable materials, but these

devices have fallen short in providing the required mechanical strength or optimal degradation profiles to avoid burst releases of acidic by-products and local inflammation.

“OSSIO*fiber*[™] Intelligent Bone Regeneration Technology has the potential to shift the paradigm in orthopedic fixation with promise for wide-ranging applications across the continuum of orthopedic surgery,” said Stuart Miller, MD, orthopedic surgeon at MedStar Union Memorial Hospital and Assistant Professor at Johns Hopkins University School of Medicine, Baltimore, MD. “An implant that maintains its strength through the known healing timeline, and is then completely integrated into the surrounding anatomy with no adverse inflammation is a real breakthrough for surgeons and the patients we treat.”

“Today’s FDA clearance of the OSSIO*fiber*[™] Bone Pin Family marks a significant milestone for our company, as we bring a new category of orthopedic fixation to the U.S. market,” said Brian Verrier, CEO, OSSIO. “We look forward to partnering with surgeons throughout the United States to integrate the OSSIO*fiber*[™] platform into their surgical treatment options, ultimately changing the current standard-of-care in orthopedic fixation by encouraging natural bone healing that avoids unnecessary hardware removal surgeries and improves the overall healthcare economics of orthopedics. This regulatory achievement supports our overall mission to transform the patient experience.”

OSSIO expects to commercially launch the OSSIO*fiber*[™] Bone Pin Family in the United States in the second quarter of 2019.

Additionally, a European multi-center clinical trial is currently underway assessing the safety and performance of the OSSIO*fiber*[™] Hammertoe Fixation Implant, with the first patient treated last month by Dr. Luke Cicchinelli at Clínica Guillén in Vigo, Spain. The trial results will serve to support the company’s Conformité Européene (CE) Mark application for approval of the OSSIO*fiber*[™] Hammertoe Fixation Implant in 2020.

The proprietary OSSIO*fiber*[™] technology can address many surgical applications through manufacturing of endless implant designs, including pins, screws and plates. The company intends to pursue multiple applications in the distal extremity, trauma, sports, reconstruction, pediatrics, and spine segments. For more information on OSSIO*fiber*[™] please visit www.ossio.io.

About OSSIO*fiber*[™] Intelligent Bone Regeneration Technology

Designed for rapid bone in-growth, regeneration and replacement, OSSIO*fiber*[™] Intelligent Bone Regeneration Technology is a first-of-its-kind implant material stronger than cortical bone that leaves nothing permanent behind. OSSIO*fiber*[™] is engineered to provide the strength required for functional fixation and allows for full integration into the native anatomy without adverse biological response. OSSIO*fiber*[™] implants utilize existing reimbursement and surgical techniques. The OSSIO*fiber*[™] Bone Pin Family represents the first of several regulatory approvals for the company and is cleared for use in the United States for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis and bone grafts in the presence of appropriate additional immobilization.

About OSSIO

OSSIO is an orthopedic fixation company committed to transforming the orthopedic experience for patients, physicians and payors. Founded in 2014, its vision is to provide the first credible replacement to metal implants in the multi-billion-dollar global orthopedic fixation market with its OSSIO*fiber*[™] Intelligent Bone Regeneration Technology. OSSIO’s development headquarters

is located in Caesarea, Israel, and its commercial headquarters is in Woburn, Massachusetts. For more information on the company visit www.ossio.io.

Forward-looking statements contained herein are based on estimates and assumptions of OSSIO management and are believed to be reasonable, though they are inherently uncertain and difficult to predict.