Orthopaedic patients face a dilemma after their fractures heal — choose a lifelong future with metal implants that may cause secondary problems or choose the option of a risky second surgery to remove implant devices. Current metal orthopedic implants made from titanium or stainless steel work well, but not without complications. nanoMAG, LLC, a Livonia, Michigan, supplier of precision magnesium sheet and short-run specialty alloys, has a better solution — biocompatible, bioabsorbable magnesium alloy implants that are strong enough to support the bone during healing and then get absorbed over time while providing nutrients to promote bone regrowth.

After three years of cooperative development with a major orthopaedic OEM, nanoMAG, has developed a novel alloy, BioMg® 250, for the enhanced fixation of fractured or restructured bones — at double the strength of commercial bioabsorbable polymer implants.

“We are a start-up biomaterials engineering firm with a 20-year legacy behind us,” explains Steve LeBeau, President of nanoMAG. “Our parent company, Thixomat Inc., has been commercializing ultra light magnesium alloys since 1989 for a variety of commercial products ranging from PC notebook bases and cell phone covers, to structural components in the automotive sector. When we shifted our focus to biocompatible alloy development, we had to throw out the cookbook and start over with a new alloy formula. All of the traditional commercial magnesium alloys contained ingredients that were considered unacceptable for a variety of biocompatibility reasons. So, we carefully selected candidate alloying ingredients friendly to the body, many of which can be found on any standard vitamin supplement bottle. After three years of development and in-vitro testing, we have developed and submitted a patent in March of 2013 for our proprietary new BioMg® 250 alloy.”

The development efforts at nanoMAG have been supported by grants from the National Science Foundation, in partnership with the University of Michigan (UoM), the University of Pittsburgh (PITT) and North Carolina State A&T University (NCAT). Currently, small animal (rabbit) studies currently are underway at NCAT, in order to measure the interaction with bones and to assure non-toxicity, and the University of Michigan has performed computerized tomography on select samples with a state-of-the-art nano-CT unit in the Orthopaedic Research Laboratories.

“We are extremely excited about the opportunities that bioabsorbable magnesium alloys provide for enhanced treatment options for orthopedic and craniofacial patients, both young and old,” said Dr. Steven Goldstein, Active Emeritus Professor (and former Research Dean of the Medical School), University of Michigan. “There is still a significant amount of testing and certification that needs to be conducted to meet FDA regulatory requirements, but this new class of materials could be a disruptive game changer in the field of orthopaedic surgery.”

Dr. Charles Sfeir, Director of the Center for Craniofacial Regeneration, is leading the team at PITT that is conducting histology evaluations of the BioMg® implants after they are harvested from the small animal studies. Figure 1 displays a cross section of a histology slide of the area immediately adjacent to a BioMg® implant.
implant after 12 weeks of exposure. “These preliminary results look very, very promising,” says Dr. Sfeir. “The histology slides provide evidence of very good integration between the bone and the BioMg® implants while it is being absorbed by the body. There are tremendous opportunities to use this new class of materials in the craniofacial dental area.”

nanoMAG, LLC is a private venture that was founded in 2009 by Thixomat, Inc, with the University of Michigan as a minority owner as part of a technology transfer agreement. nanoMAG uses a business development approach to OEMs to jointly engineer and develop a specific application. The OEM develops and validates unique proprietary designs to meet structural demands for each market application. Then, the OEM contracts with nanoMAG to produce the part in volume. nanoMAG develops new biomedical pins, screws, plates, and fixtures, and sells the finished part or set to OEMs such as Stryker, Biomet, or J&J, etc. The partner will then take the product through early animal validation studies, through FDA regulatory approval, and ultimately market and distribute the product. nanoMAG creates value by developing and manufacturing the medical device implants with unique chemical composition and structural characteristics to meet specific surgical procedures and patient requirements.

“Michigan is a great place to launch a new business in the medical device market space.”

nanoMAG has established key relationships with major OEMs in the biomedical space. Over the past six months, nanoMAG has entered negotiations with five Tier 1 OEMs regarding funded cooperative development projects, all with unique market applications. Although our primary focus is the biomedical implant market opportunity, we have secondary market opportunities which are generating early sales revenue and partnerships with our biomedical customers. These secondary markets include external fixation devices and braces, as well as surgical tools. In February 2012, DJO Global ($388M revenues in external bracing in 2011), launched a new external knee brace. The new knee brace, the “OA Nano” is the lightest knee brace on the market for treating osteoarthritis. The product was co-developed taking full advantage of the mechanical and physical attributes of nanoMAG high strength alloy sheet.

“We could not have made the substantial progress we have achieved to date without the assistance of our extended network of external advisors and collaborators,” said LeBeau. “Michigan is a great place to launch a new business in the medical device market space. We have benefitted greatly from collaboration with local universities, Ann Arbor SPARK, MichBio and countless individual technical and commercial supporters, and we were fortunate enough to not only experience the networking opportunities of the Accelerate Michigan Innovation Competition, but we managed to come in second place last year that provided us with $100,000 of early stage seed money.”

For more information on nanoMAG, visit www.nanomag.us or contact Steve LeBeau at slebeau@nanomag.us.

**Figure 1:** Summary of histology slides showing evidence of bone formation (purple contrast) in intimate contact with a BioMg® implant (white) after 12 weeks in-vivo testing, (courtesy of the University of Pittsburgh).