OSTEOFUSE, LLC, BONE HEALING SOLUTION
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Industry Sector(s): Healthcare, Orthopedic surgery
Product Category: Pharmaceutical

Opportunity Overview

Over a period of three years, and funding of ~$2M, Osteofuse has developed a novel bone healing solution to address high risk problematic fractures thereby potentially improving the quality and cost of orthopaedic surgery. This is novel technology that represents a disruptive innovation in the medical field with preliminary results suggesting potential demand for our product in both existing markets (i.e. replacing BMPs), and potentially expanding its application to new previously untapped markets. From a clinical perspective, there is a significant demand for for this product to safely augment bone growth (fracture healing, spine fusions, etc). There is also a compelling economic value proposition with the product, important in a health care climate increasingly focused on the economic impact of different medical interventions.

Markets & Applications

This is novel technology that represents a disruptive innovation in the medical field with preliminary results suggesting potential demand for our product in both existing markets (i.e. replacing BMPs), and potentially expanding its application to new previously untapped markets. Sales of bone growth proteins (BMP-2/7) are approximately $900MM. Growth was 10-20% per year until recent FDA concerns over increased cancer risks, autoantibody development, and investigations of illegal marketing practices have diminished expectations. Nevertheless, from a clinical perspective there is a significant demand for a product that would safely augment bone growth (fracture healing, spine fusions, etc). There is also a compelling economic value proposition with the product, important in a health care climate increasingly focused on the economic impact of different medical interventions.

Competitive Advantage/Value Propositions

Orthopaedic surgeons believe there is limited future innovation for metal implants and that significant advances in bone healing will require pioneering application of biologic agents for the repair of bone and soft tissue injuries and disease. The research results suggest that scaffolds delivering thrombopoietic agents may be a novel and efficacious method of providing a biologic solution to orthopaedic problems. This research represents a significant “out-of-the-box” type innovation as current thrombopoietic agents are FDA approved for systemic (subcutaneous injection) administration to increase megakaryocyte (MK) production and the collagen sponge is also FDA approved for use.
with BMP-2 for tibial shaft fractures. Here, thrombopoietic agents are used in an entirely different way (local administration) and for a different purpose (local bone healing). Indeed, we believe this would be the first time a MK stimulating agent has been proposed for use in human fractures.

**Researcher Biographies**

**Melissa A. Kacena, Ph.D.**
Dr. Kacena has been an Assistant Professor of Orthopaedic Surgery, Indiana School of Medicine since 2007. She received her Ph.D. in Aerospace Engineering from the University of Colorado, Boulder in collaboration with Harvard Medical School and NASA Ames Research Center. She completed her postdoctoral training in the Department of Orthopaedics and Rehabilitation at Yale University School of Medicine. While at Yale she was promoted to Assistant Professor of Orthopaedics and Rehabilitation. Her current IU laboratory’s overall research goal is to improve the understanding of the interaction of the bone and hematopoietic systems, thereby potentially improving the treatment of metabolic bone disease, hematopoietic disorders, and fracture healing. To achieve this goal, our research focuses in five areas: 1) The role of megakaryocytes, megakaryocyte growth factors and their receptors in bone homeostasis; 2) Osteoblasts and the hematopoietic stem cell niche; 3) Regulators of osteosarcoma tumor growth; 4) Translational/clinical studies examining the genetic regulation of skeletal homeostasis; and 5) The molecular mechanisms underlying bone repair/fracture healing. Dr. Kacena has received numerous honors, young investigator awards, and grants for her research, including NIH funding.

**Tien-Min Gabriel Chu, DDS, Ph.D.**
Dr. Tien-Min Chu received his Doctor of Dental Surgery degree from Kaohsiung Medical College in Kaohsiung Taiwan in 1989. He later received his PhD in materials science and engineering from the University of Michigan, Ann Arbor, Michigan in 1999. He is currently an Associate Professor of Dental Biomaterials at the Indiana University School of Dentistry where he also holds adjunct appointments at Department of Biomedical Engineering and Department of Orthopedic Surgery. Dr. Chu’s current research activities mainly fall into two areas: Bone tissue engineering and the in vivo dental implant evaluations. His work in bone tissue engineering focuses on the manufacturing and characterization of load-bearing biodegradable scaffolds for bone regeneration. In this area, he has received support from NIH and has published in top ranking biomaterial and tissue engineering journals. He is also working on the development of stem-cell seeded 3D biodegradable scaffolds for craniofacial regeneration. Finally, Dr. Chu has also established his research program in the in vivo evaluation of dental implant. He has received over half a million funding from industries as well as other dental school to conduct in vivo evaluation of several novel dental implants. Dr. Tien-Min Chu is currently a member of the American Association of Dental Research, Society for Biomaterials and Academy of Dental Materials.

**Development Plans/Needs**

1. Establish contacts with live large animal (i.e. larger than rodent model, specifically minipig or dog studies) facility/laboratory representatives around the state of Indiana that are Good Laboratory Practice (GLP) certified and able to conduct pharmacokinetic (PK) studies required by the FDA for large animals.

2. Establish contacts with FDA consultants/specialists who have experience getting similar drug/device/combination approvals for clinical trials and understand what specific requirements must be met.