Evoke Medical, LLC: *PiezoNail* -- Stimulating a Pathway to Better Fracture Healing

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Technology: Delayed unions and nonunions of bone fractures are common complications in orthopedic medicine, with up to 10% of 6 million fractures developing a form of nonunion [1]. With the goal of decreasing healing time and risk of delayed or nonunion, Evoke Medical will use our platform technology of mechanically synched direct current (DC) electrical stimulation using embedded piezoelectric composite biomaterials to improve healing of long bone fractures with each step the patient takes. All Evoke Medical implants aim to have similar external appearances and biomaterials as the existing device that it will replace, thus reducing regulatory barriers and eliminating the need for additional surgeon training. Proof of concept ovine studies using a piezoelectric composite embedded in a spinal interbody implant showed that lumbar fusion can be greatly enhanced with mechanically synched DC electrical stimulation [2]. Evoke Medical currently has NIH SBIR Phase II funding to help bring the piezoelectric spinal fusion implant to market. With clever implant design, mechanically synched DC stimulation can be used in any orthopedic implant to help heal fractures or promote bony ingrowth.

Our second product, *PiezoNail*, is an intramedullary (IM) nail fracture fixation device with an embedded piezoelectric composite to generate mechanically synched DC stimulation to aid in long bone fracture healing. Over 235,000 fractures occur in the femur and tibia in the US every year. Orthopedic surgeons often use IM nails to stabilize these types of fractures and ensure proper alignment of the bone. IM nails are the fastest growing trauma segment with a current annual growth rate (CAGR) of 4.7% [3]. Among this large population of IM nail procedures, patients who are tobacco users or diabetic are among the hardest to heal. DC electrical stimulation has been shown to increase the rate of healing for these difficult to fuse patient populations [4]. Using our novel platform technology, Evoke Medical will incorporate piezoelectric composites into a modular IM nail design to increase the success rates of long bone fracture fixation and decrease the rate of delayed and nonunion.

Market: IM nailing procedures totaled 214k in 2016, accounting for $658 M of the $1.7 B trauma market. The IM nail market is the fastest growing with a CAGR of 4.7%, with a predicted market size of $785 M in 2020.

Commercialization Strategy:

Regulatory: Evoke Medical is currently pursuing a DeNovo pathway for our piezoelectric spinal fusion implant, with anticipated granting in early 2021. The DC stimulation aspect of that product will then serve as a predicate for future Evoke Medical products such as the IM nail. Work is underway for design and testing of *PiezoNail*, the Evoke Medical piezoelectric IM nail. Evoke Medical's regulatory strategy for the *PiezoNail* is to use existing IM nails, the compression hip screw, and its piezoelectric spinal fusion implant as predicates for a 510(k) regulatory pathway.

Manufacturing: Evoke Medical has partnered on an equity basis with two companies with expertise in piezoelectric energy harvesting and piezoceramic manufacturing. We will contract with an ISO 13485 compliant manufacturing firm to fabricate the modular metal components of the IM nail. Evoke Medical will assemble the piezoelectric composites with the modular metal components and perform non-destructive testing of DC signal generation for additional quality control.

Marketing: After obtaining FDA clearance, *PiezoNail* will be marketed as a bone healing device for use in long bone fracture fixation. With its greater ability to heal large bone gaps, *PiezoNail* will be attractive to the DoD for treatment of highly comminuted fractures experienced by our wounded soldiers in IED explosion injuries to the lower extremities. Once in the military market, it will be easier to enter the private sector with greater indications so that marketing for use in difficult to fuse patients such as smokers and diabetics can be emphasized.

Finances: Evoke Medical is currently seeking funding from the DoD and will submit proposals to NIH for SBIR funding to aid in manufacturing, verification and validation testing, and a large animal pre-clinical study. After successful results are achieved in the proof of concept study, venture capital will be sought to facilitate regulatory clearance and scaled up manufacturing to bring this revolutionary concept to market.

Profits: Addition of a piezoelectric in the *PiezoNail* design will increase cost of goods sold. However, the *PiezoNail* design incorporates cost-saving features for scale-up manufacturing that will minimize this increase. Accurate profit estimations cannot be made at this time.

Reimbursement: The primary function of *PiezoNail* is as an IM nail, thus allowing for use of current IM nail CPT codes for reimbursement. As clinical studies prove its utility in treating tobacco users and diabetics, additional indications will be obtained. A premium in price can be paid with addition of these indications, while new higher-level reimbursement CPT codes are sought for the enhanced healing capability.

Exit Strategy: Once proof of concept is obtained, *PiezoNail* development complete, and regulatory clearance granted Evoke Medical will either grow its manufacturing and distribution capability, or license *PiezoNail* to a major orthopaedic fracture fixation company. Evoke Medical will continue work on the novel piezoelectric platform technology to develop other enhanced bone healing implants to help ease pain and suffering of patients.

References: [1] Rupp, Markus et al, Int Orthop, 2018; 42: 247-258. [2] Friis et al. Trans 2015 SFB. [3] SmartTRAK Life Sciences Business Intelligence. [4] Zimmer-Biomet SpF® Online Surgical Tech, 2018.