Evoke Medical: Stimulating a Pathway to Bone Healing

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Technology: With the Affordable Care Act, reimbursement to hospitals for procedure costs is dependent upon patient outcomes. Hospitals are eager for innovations that provide shorter surgery time, shorter recovery time, and higher success rates for treatments and procedures. Evoke Medical will use a platform technology of a tough piezoelectric composite material to create loading-bearing implants that use a patient's own motion and loading to produce direct current (DC) electrical stimulation to help promote bone healing.

Our first product is eHeal, a lumbar spinal fusion interbody device that uses DC stimulation to help promote successful fusion. Over 600,000 spinal fusion surgeries are performed each year in the USA, of which about 60% are for patients in the high risk or difficult-to-fuse category (e.g., smokers, diabetics). Successful spinal fusion rates in the difficult-to-fuse population have been shown to be as low as 50-70% [1]. Direct current (DC) electrical stimulation has been used clinically to stimulate bone healing for over 25 years without adverse events or ectopic bone formation. There is one clinically available device set that provides DC stimulation to promote spinal fusion (Biomet SpF®). It requires a second surgery site to implant the battery pack, has electrodes over the transverse processes, and may require a later surgery to remove the battery pack. An alternative solution is an interbody device that incorporates a load-bearing tough piezoelectric composite material. Theoretical models have shown that a piezoelectric implant can generate the needed electrical stimulation levels for bone healing through the natural motion and loading of the body [2]. Bench-top testing showed that power levels sufficient to provide electrical stimulation levels to promote bone healing could be achieved in a composite piezoelectric implant [3,4].

A pilot proof of concept study in two sheep showed that the active piezoelectric composite interbody device had faster and better quality fusion bone than a size, shape and mechanical property matched non-stimulating control. While this pilot study could not be evaluated on a statistical basis because of the small sample size, the results are extremely encouraging and provide sufficient evidence for Evoke Medical to proceed with larger animal trials and commercialization activities.

Market: The total US spinal fusion market is over $1.25B, which corresponds to over 600,000 procedures annually. The CAGR was 4% in 2011 and is expected to rise along with the increase in aging population.

Commercialization Strategy:

Regulatory Approach: Evoke Medical's regulatory strategy for eHeal will be to submit the product along a 501(k) pathway with a PEEK fusion cage as the predicate device. Most interbody cages are regulated as Class II devices. Even though DC electrical stimulation is also a product feature in eHeal, the primary mode of use is as a fusion cage, thus steering the Class II designation.

Manufacturing: Evoke medical will license intellectual property for the manufacturing of the piezoelectric composite biomaterial. Scale-up manufacturing techniques for eHeal will be first developed in-house then executed with our ISO 13485 compliant manufacturing partner off-site.

Marketing: After receiving FDA clearance for eHeal, Evoke Medical will market the interbody fusion implant for use in all patients to help decrease the time to fusion for all patients and rate of fusion for the difficult-to-fuse population. Evoke will form relationships with independent distribution and medical device sales companies who will in turn sell the product to hospitals.

Finances: Evoke Medical will initially seek NIH SBIR funding to develop scale-up manufacturing technique, translate these techniques to our manufacturing partners, and perform large animal proof of concept studies to achieve statistical significance. Venture financing will be sought to fund scale-up manufacturing and regulatory clearance.

Profits: eHeal profits will depend on COGS and market share and cannot be accuracy estimated at this time.

Reimbursement: Spinal fusion and electrical stimulation are generally considered medically necessary and are reimbursed. Both procedures have existing CPT codes, allowing for an easier reimbursement pathway.

Exit Strategy: The current Business Model Canvas plan for Evoke Medical is shown in Figure 1. Evoke Medical will develop eHeal as its first product base and will plan for licensing acquisition of that product line by a major spine implant company after initiation of sales. Evoke Medical will continue to develop and license new product lines based on its platform technology.

References: 1. Kucharzyk DW et al., Spine. 1999; 24(5):465-8. 2. Tobaben et al., JBMR-A, 2014. 3. Goetzinger NC, Thesis, Univ. of KS, 2014. 4. Tobaben NJ, Thesis, Univ. of KS, 2014.

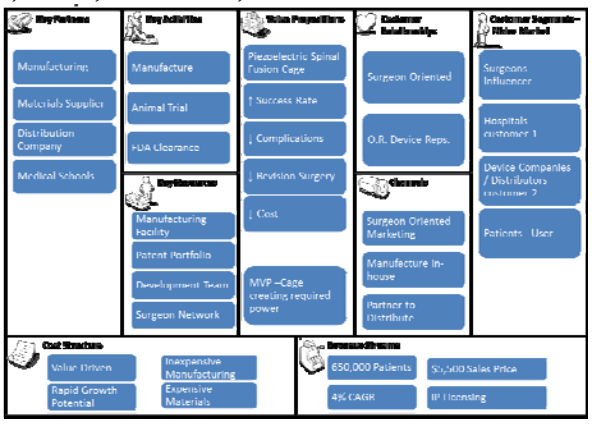

Figure 1. Business Model Canvas for Evoke Medical.