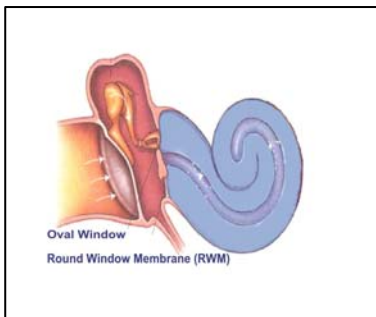




## OAD Technology for Inner Ear Therapeutics

**Overview:** NanoBioMagnetics, Inc (NBMI) is a *nanobiomaterials* company focusing on the development and commercialization of nanotools that enable and enhance the advancement of human health treatment methodologies. The company is pioneering an emerging area of nanomedicine referred to as Organ-Assisting-Device (OAD) technologies, in which magnetically responsive nanoparticles, under the influence of shaped external magnetic gradients, are caused to drive a desired physiological event. The company's OAD applications, developed and validated in collaborations with major research institutions, are being



advanced under two proprietary technology platforms: (1) **Vectored Drug Delivery**, in which designed therapeutic constructs are magnetically vectored to the site of therapeutic need, and (2) **Biostable Implants**, in which implanted constructs drive tissue movement or vibration in an oscillating magnetic field. OAD healthcare applications have been validated in preclinical models, where scientific firsts have been achieved. The company is now developing partnerships with healthcare and pharmaceutical organizations that will support the commercial development of these technologies.

**Introduction:** NBMI scientists, under a CRADA with the Office of Naval Research, demonstrated in a small animal model, in a **scientific first**, that magnetically responsive nanoparticles, under the influence of an external magnetic gradient, can be drawn atraumatically across the Round Window Membrane (RWM) into the cochlea. The attachment of biologically active compounds to magnetically responsive nanoparticles offers the potential for a disruptive therapeutic delivery methodology which does not currently exist (**Patent Pending**).

As an example, researchers at other institutions have demonstrated that certain genes, transported by viral vectors, have the capacity to restore hearing in deaf mammals. However, the viral delivery method employed is not feasible for human health applications. This negative property can be overcome by coupling the specific gene to magnetically responsive nanoparticles, and using magnetic gradients to pull the construct across the RWM with distribution throughout the cochlea. The anticipated expression and regeneration of ear sensory cell growth leads to a new treatment modality for inner ear hearing loss. For the patient, the cost/benefit impact would be quite significant.

**Commercialization Focus:** As a delivery mechanism for treating inner ear disorders, this technology has the potential to become a standard treatment modality. The capacity for

targeted delivery of therapeutics to the inner ear, without trauma to the organ, offers significant potential for advanced treatment options not currently available. The loss of sensorineural cells in the cochlea results in significant degrees of hearing loss – deafness, which affects approximately 6 – 8 million Americans. Of this population approximately 2 million benefit from cochlear implants. With respect to Economics, this is an expensive surgical procedure where both performance and compliance issues are significant factors. At present, cochlear implantation is a hospitalization procedure with average costs of approximately \$50,000. While significant hearing improvement is achieved with cochlear implants, the patient cost/benefit ratio remains significantly high.

The successful validation NBMI's magnetic vectoring technology offers the potential for **sensory cell remediation/regeneration**, in which therapeutic constructs, including genetic materials, will be delivered atraumatically into the cochlea.

The company is moving to establish a research collaboration that will include long-term toxicity studies, and develop a prototype system that would be evaluated in a clinical model. It is estimated that 3 – 5 years of development and clinical effort will be required to move this technology through FDA requirements to the commercialization pathway

**Advantages:** The patient cost/benefit ratio is affected in the three key areas of Economics/Performance/Esthetics:

- Economics: Less trauma and invasive procedures required in the delivery of therapeutics to the inner ear. Compatibility with middle ear devices will also improve performance.
- Performance: The direct regeneration/remediation of ear sensory cells has profound implications for the deaf community.
- Esthetics: Advancements in totally implantable devices, being driven by magnetic nanoparticle technology, will lead to greater patient compliance.

**Partnerships:** NBMI is seeking a joint development partnership with a major healthcare organization with the vision and capacity for supporting the development and commercialization of new disruptive technology based on NBMI's OAD technology for the delivery of inner ear therapeutics.

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