

## **Press Information**

### **AOI Medical, Inc. Treats Thirty (30) Patients in Ascendx™ VCF Reduction System Clinical Trial**

#### ***Procedure Designed to Provide a Mechanical, Repeatable Cutting of Cancellous Bone and to Provide Even Distribution of Bone Cement***

London, UK, 31 March 2009 – [AOI Medical, Inc.](#) (the “Company” or “AOI”) (AIM: AOI), a medical device company focusing on innovative orthopaedic medical devices for the spine and trauma markets, has successfully completed surgical procedures on thirty (30) patients in a clinical trial with Ascendx™ Vertebral Compression Fracture (“VCF”) Reduction System (“Ascendx™”) at six sites across the United States. The board is pleased with the progress of the clinical trial and results to date; evaluation of clinical outcomes is ongoing.

William J. Christy, CEO of AOI Medical, said: “The clinical program has gained momentum and we are pleased with our progress to date. The Ascendx™ system is designed to provide notable improvements in the way physicians traditionally treat VCFs. While all currently existing VCF procedures offer immediate pain relief to the patient, the Ascendx™ technology is specifically designed to provide a mechanical, repeatable cutting of cancellous bone and to deliver an even distribution of the bone cement.” Over time, these features may potentially provide benefits with respect to clinical outcomes, subject to ongoing clinical evaluation.

On 12 March 2008, AOI received final approval from the FDA to commence a clinical trial for its Ascendx™ technology. The single arm trial of Ascendx™ will ultimately involve sixty (60) subjects in eight centers, with the primary end point being acute procedural success defined as successful device deployment, cement delivery, and device withdrawal. The data from the trial will be used as clinical support for the company’s 510(k) submission to the FDA in relation to Ascendx™.

The clinical trial is expected to complete its last patient enrollment and make its 510(k) submission to the FDA in mid-2009. The company believes that it remains on target for a market launch of Ascendx™ in the United States towards the end of 2009.

#### **About Ascendx™**

Ascendx™ is an investigational device which comprises a set of tools specifically designed for use in the treatment of painful pathological fractures of the vertebral body that may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancers and myeloma. Ascendx™ will comprise two main instruments: a cutting device that creates a cavity in cancellous bone, and a reduction device that is used to restore the height of the fractured vertebra and which can deliver and contain the bio-material (bonding agent) in the cavity. The set of tools is designed to offer a potential enhancement over current techniques. Ascendx™ is an investigational device limited to investigational use in the ongoing IDE study in the United States.

Ascendx™ presents an attractive market opportunity. The size of the market is estimated to be in the region of \$700 million annually, rising to over \$900 million by 2012 (source: CRT Capital, LLC 2008).

**About AOI Medical, Inc.**

AOI is a medical device company focusing on the development and commercialisation of innovative orthopaedic medical devices for the spine and trauma markets. It is progressing the development of three separate innovative product platforms: Ascendx™ VCF Reduction System, BAMF Trauma and Cervical Plate. Further information can be found at [www.aoimedical.net](http://www.aoimedical.net)

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