

## **Press Information**

### **AOI Medical, Inc.**

#### **BAMF Spine Product Update**

London, UK, 26 October 2007 - AOI Medical Inc. (the "Company" or "AOI") (AIM: AOI), the medical device company focusing on innovative orthopaedic medial devices for the spine and trauma markets, today announces that the US Food and Drug Administration ("FDA") has asked AOI to conduct a clinical study of its BAMF Spine technology. Full details of the content and timing of the study are presently being negotiated with FDA and AOI will provide an update on those negotiations once completed. As described in the Company's Admission Document, the Directors had anticipated the FDA regulatory path may include clinical information to support the 510(k) application. While the ultimate path is not clear, AOI Medical currently has a plan in place to respond to the FDA.

The study will be designed to support substantial equivalence of the BAMF Spine technology. Study endpoints will include successful deployment and cement delivery, as well as clinical outcome measures. As a result of this decision, the commercial launch of BAMF Spine in the US is now expected to occur in H2 2008.

BAMF Spine is an investigational product which provides a set of tools intended to be used to address compression fractures of the spine caused by osteoporosis, cancer or trauma. BAMF Spine will comprise two main instruments: a cutting device that creates a cavity in cancellous bone, and a balloon-like device which is used to restore the height of the fractured vertebra and to deliver and contain the cement in the cavity. The set of tools is designed to offer a potential enhancement over current techniques.

Current techniques used to treat progressive vertebral compression fractures include vertebroplasty and kyphoplasty (so named by Kyphon, the company that developed the technology). In July 2007, it was announced that Medtronic (NYSE:MDT) had acquired Kyphon for \$3.9 billion. This acquisition fully underpins the market opportunity that lies within this area as patients and doctors continue to seek modern, minimally invasive spinal treatments that enhance patient life-styles and are simpler, faster and less-invasive than the traditional surgical treatments. The Directors of AOI believe that the Company has a product that can significantly challenge the current products on the market.

In 2004, the worldwide market for devices targeted towards spinal conditions had a value of around \$3.5 billion and most recent estimates indicate that the spinal products market will approach \$10 billion by 2010. The growth is being driven by increasing incidences of osteoporosis in an ageing population and a growing number of sports related injuries as people become more active. In 2009, the BAMF Spine global market size is estimated to be over \$500 million.

Bill Christy, CEO of AOI, said:

"We believe the clinical study requested by FDA will demonstrate the successful performance and ease of use of the BAMF System. The Company is prepared to begin the study immediately upon FDA's issuance of the investigational device exemption. A clinical study will provide the Company with useful clinical data with which to support future marketing activity."

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**Background to AOI Medical Inc.**

AOI is a medical device company focussing on the development and commercialisation of innovative orthopaedic medical devices for the spine and trauma markets. It is progressing the development of three separate technology platforms: BAMF Spine, BAMF Trauma and Cervical Plate.

Further information can be found at [www.aoimedical.net](http://www.aoimedical.net)