

## **Press Information**

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

#### **BAMF Spine Regulatory Update**

London, UK, 8 October 2007 - AOI Medical Inc. (the "Company" or "AOI") (AIM: AOI), the medical device company focusing on innovative orthopaedic devices for the spine and trauma markets, today provides an update on regulatory progress with its BAMF (Balloon Assisted Management of Spine Fractures) Spine product, following 510(k) submission to the US Food and Drug Administration ("FDA") in July 2007.

Following recent constructive dialogue between the FDA and AOI, the FDA has extended the consultation period for a further 90 days before deciding whether to give the Company approval to market BAMF Spine in the United States. AOI has appealed to the regulator following receipt of a letter from the FDA requesting a confirmatory study. The FDA has now agreed to give further consideration to the necessity of a clinical trial, resulting in the extended consultation period.

The Company expects to meet with the FDA again in late October and expects to get clarity on the outcome shortly thereafter. A further announcement will be made once a decision has been made.

As a result of this revised timetable, the commercial launch of BAMF Spine in the US is expected to occur either in Q1 2008 if no clinical trials are required or H2 2008 if trials are required.

As previously disclosed, AOI has always been aware that the FDA may require the clinical data for BAMF Spine and as a result made budgetary provisions at the time of the IPO for a limited clinical trial in this area. AOI Medical now has in place, through its established clinical advisory panel, the clinicians who would conduct the operations for the confirmatory study. The Company has already successfully demonstrated the BAMF Spine procedure on a number of osteoporotic [cadaver] spines in the laboratory and the Directors are confident that this success will be demonstrated in the clinical trial.

BAMF Spine is 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. Current techniques used to treat progressive vertebral compression fractures include vertebroplasty and kyphoplasty. The Directors believe that BAMF Spine represents an enhancement over the current techniques as they expect the process: to be accomplished through one pedicle access port (incision) rather than two; to require fewer steps and less time; to be less susceptible to cement leakage; and to return the fractured vertebra to true anatomic position.

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 Medical 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 Medical, said:

*“We have been encouraged by the dialogue to date with the FDA and believe that the additional 90 days will allow us to further strengthen our case with the regulator. We remain convinced that BAMF Spine is a high quality technology addressing a major market need with limited competition. We look forward to moving the product towards market and keeping shareholders informed of progress.”*

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**Background to AOI Medical**

AOI Medical 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)