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AOI Medical, Inc.
(“AOI Medical” or “the Company”)

AOI Medical announces 510 (k) submission for BAMF Spine

Remains on track to achieve commercial launch by end of 2007

AOI Medical, the medical device company focussing on the development and commercialisation of innovative orthopaedic medical devices for the spine and trauma markets, today announces that it has successfully processed its 510 (k) submission for BAMF Spine (Balloon Assisted Management of Spine Fractures), in line with the Company’s commercial strategy and timeline.

The submission was made following the development earlier this year of devices for biomechanical tests. Due to the existence of predicate materials and devices having successfully attained FDA approval, the submission was made without supporting clinical data, consistent with standard market practise. Subject to the FDA approving the 510 (k) submission by the fourth quarter of 2007, the BAMF Spine procedure is expected be launched by the end of 2007.

BAMF Spine is a set of tools designed to address compression fractures of the spine caused by osteoporosis or trauma. The Company anticipates that BAMF Spine will represent an enhancement over current techniques as the process:

- will be accomplished through one pedicle incision rather than two;
- will require fewer steps and less time than incumbent procedures;
- will prove less susceptible to cement leakage; and
- will return the fractured vertebra to true anatomic position.

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.

The Company floated on the Alternative Investment Market (AIM) of the London Stock Exchange on 22 June 2007.

William Christy, Chief Executive Officer of AOI Medical, said:

“It is pleasing to be able to deliver on one of our milestones so soon after coming to AIM. We are hopeful that the FDA will not require clinical data and that we will therefore be able to launch BAMF Spine before the end of this year. However, if clinical data is required we have budgeted for that.

“BAMF Spine represents a significant enhancement over current methods of treating spine fractures, which are becoming a growing problem.”

Enquiries:

AOI Medical, Inc.	+1 407 770 1800
William Christy, CEO	
Numis Securities	+44 (0)20 7260 1000
David Poutney / Bruce Garrow	
Financial Dynamics	+44 (0)20 7831 3113
Ben Atwell / Ben Brewerton	

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.

The Products

BAMF Spine (Balloon Assisted Management of Spine Fractures): a set of tools intended to be used to address compression fractures of the spine caused by osteoporosis 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.

BAMF Trauma (Balloon Assisted Management of Trauma Fractures): is a removable, inflatable nail for the stabilisation of fractures of the long bones of the arms and legs. AOI's BAMF Trauma differs from the nails currently on the market in that it is a combination of a stainless steel nail inside a balloon. The device is inserted into the intramedullar canal of the fractured bone with the balloon deflated. The balloon is then inflated to fill the remaining space. The Directors believe that BAMF Trauma will have a technological advantage over existing products in the market because it will potentially: require a smaller gauge at the point of insertion; provide a firm structure, adapted to the bone cavity while in place; and be easily removed by deflating the balloon, thus narrowing the diameter of the device again. The Directors believe that this last feature should make the device particularly interesting for treating children, in whom growth in the affected limb is impaired if a stabilisation device is left in place.

Cervical Plate (Motion Preserving Cervical Dynamic Stabilisation Plate): an anterior, semi-constrained artificial ligament designed to provide some translational and rotational motion when used subsequent to a cervical spine disc replacement surgery. Current practice for severe intractable disc disease is spinal fusion. Spinal fusion is a medical procedure by which two or more vertebrae are linked together. Fusion may be carried out to treat a number of spinal conditions; however, it causes stiffness of the spine in patients and increases stress to the adjacent levels of the spine which may lead to additional morbidity. The failure rate after lumbar fusion has been reported to be as high as 37 per cent. Anterior plates provide stability following decompression and fusion of the cervical spine. The Directors believe that the following technical attributes of the Cervical Plate provide it with a technological advantage over existing spinal fusion techniques: it offers a motion preservation fusion approach that aims to promote a return to normal range of motion when used in combination with alternatives to fusion; the sculpted design and thickened rails of the Cervical Plate should allow the support needed to allow multi-directional movement while ensuring disc compression, reducing pressures across adjacent parts of the spine; and it is a smaller device than competitive devices and should therefore be less disruptive.