

# Bone Medical

ASX/MEDIA RELEASE

## **Bone Medical approval to start phase I/IIa trial for second osteoporosis drug**

*Ethics approval for Queensland human trial*

**21 August 2007:** Bone Medical Limited (ASX:BNE) has received Ethics Committee approval to proceed to Phase I/IIa trial for the company's second lead product for osteoporosis called Perthoxal®.

The clinical trial will be conducted in Brisbane Australia by QPharm on 8 healthy post menopausal women. Perthoxal® is expected ultimately to be approved for use in late stage osteoporotic patients.

"The positive news on Perthoxal® proceeding to Phase I/IIa clinical trial is an important milestone and further validation of Bone Medical's ability to progress clinical candidates," said Bone Medical's managing director Troels Jordansen.

"We expect to be able to initiate the trial in September 2007 and to publish results in Q1 2008."

"As Perthoxal® is using the same drug delivery technology as the company's oral calcitonin, which has just successfully finalised Phase IIb, we are hopeful to demonstrate a biological effect and be able to progress the product to the Phase IIb trial stage later in 2008."

The drug is parathyroid hormone peptide (PTH). The trial is a single-blind cross-over trial to evaluate the effectiveness of two different formulations at two different doses. Bone Medical will be using Axcress™, Bone Medical's novel oral peptide delivery system.

### **About parathyroid hormone peptide**

PTH is one of the principal controlling agents for the maintenance of normal calcium levels in the blood. Oral PTH could replace injected PTH (currently on the market for 2-3 years and estimated to sell US\$600 million in 2007) and expand the market through greater patient acceptance.

Perthoxal® may target sections of the osteoporosis market which had total world sales exceeding US\$9 billion in 2005 and is projected to be US\$ 10 billion by 2007.

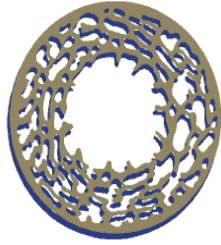
Currently, injectable PTH is the only product in the world accepted by the US Food & Drug Administration (FDA) to be able to build bone.

### **About osteoporosis**

Osteoporosis is a condition in which the bones become fragile and brittle leading to a higher risk of fractures (breaks or cracks). Osteoporosis occurs when bones lose minerals such as calcium more quickly than the body can replace them, leading to a loss of bone thickness (bone mass or density).

As a result, bones become thinner and less dense, so that even a minor bump or accident can cause serious fractures. Any bone can be affected by osteoporosis but the

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most common sites are bones in the hip, spine, wrist, ribs, pelvis and upper arm. Osteoporosis usually has no signs or symptoms until a fracture happens - this is why osteoporosis is often called the 'silent disease'.

Every 8 minutes, someone is admitted to an Australian hospital with an osteoporotic fracture. 1 in 2 women and 1 in 3 men are expected to have an osteoporotic fracture in Australia.

- ENDS -

## Enquiries:

Dr Roger New  
Chairman

Mobile: +44 781 806 8012

Australian Office: +61 8 9355 5123

Rudi Michelson

Monsoon Communications

03 9620 3333

Troels Jordansen

Managing Director

Mobile: + 44 79 1713 0019

Or visit: [www.bonemedical.com](http://www.bonemedical.com)

## About Bone Medical Limited

Bone Medical Limited is an international biopharmaceutical development company positioned to exploit the growing market in the treatment of bone disease particularly in osteoporosis and arthritis. Bone has a portfolio of biopharmaceutical development projects for the treatment of bone disease including,

### Osteoporosis

- Capsitonin™ oral calcitonin
- oral parathyroid hormone
- bone cell regulators BN005 & BN008

### Arthritis

- TNF regulators BN006
- joint protection & collagen tolerance BN007