

# Bone Medical

ASX/MEDIA RELEASE

## **Bone Medical receives US FDA guidance on osteoporosis drug**

*Recommendations provide clear path towards Phase III trial*

**19 August 2009:** Bone Medical (ASX:BNE) has received a formal response from the US FDA to the IND application filed in June for Capsitonin™, its oral formulation of the approved osteoporosis drug salmon calcitonin.

In their response, the FDA has advised that Bone Medical now has an open IND and identifies pathway the Company can undertake including a 12-month Phase III study with a primary endpoint of change in bone mineral density, avoiding the need to focus on collecting bone fracture data in multi-year studies, as is required with new drugs for this chronic condition. The response also indicates a requirement for modest non-clinical data regarding pharmacokinetics and toxicology; this is as expected due to the nature of the oral formulation that specifically avoids any new chemical entities.

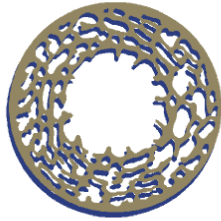
Leif Jensen, Bone Medical's Chairman, commented, "The FDA response is consistent with our earlier communications with the Agency and provides clarity not only for the Company but also for potential pharmaceutical partners and investors."

Prior to commencing the Phase III study Bone Medical intends to undertake further work on the scaling-up of the Capsitonin™ GMP manufacturing process and to generate further data identifying the appropriate dose levels to be used in the study.

Bone Medical will also be pressing ahead with the filing of an additional IND application for Capsitonin™ for the treatment of osteoarthritis. This is a substantial market where there is a great need for a safe product which alleviates bone pain.

Roger New, Bone Medical's Chief Scientific Officer added, "The requirement by the FDA for only limited additional safety data is very encouraging not only for the osteoporosis indication but also for the osteoarthritis indication. We believe that we will also be able to develop Capsitonin™ for the treatment of osteoarthritis within a few years."

**ENDS**



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## **Enquiries:**

Leif Helth Jensen  
Chairman  
Mobile: +45 4052 0787

Dr Roger New  
Chief Scientific Director  
Mobile: +44 781 806 8012  
Australian Office: +61 8 9355 5123

Rudi Michelson  
Monsoon Communications  
+61 3 9620 3333

[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
- · CaPTHymone™ oral parathyroid hormone
- · bone cell regulators BN005 & BN008

### **Arthritis**

- · TNF regulators BN006
- · joint protection & collagen tolerance BN007