



# Bone Medical

ASX/MEDIA RELEASE

**Bone Medical Phase II Capsitonin™ (oral calcitonin)  
in 35 patients – positive primary endpoint CTX-1 data**  
*CTX data showing Bone's capsule is as effective as nasal version*

**1 August 2007:** Bone Medical Limited (ASX:BNE) announces that further positive data (BNE announcement 19 July 2007) has emerged from the repeat-dose clinical trial testing of its oral calcitonin formulations (Capsitonin™) for osteoporosis conducted by Q-Pharm in Brisbane Australia.

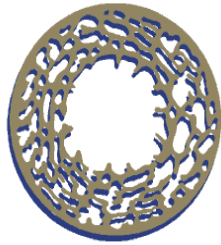
Bone recently reported that biological efficacy had been demonstrated on the basis of changes in calcium levels after administration of a single capsule on day 1. Further analysis has indicated that, according to this criterion, both 1,250 i.u. and 2,500 i.u. doses of Bone's lead candidate formulation show equivalent activity to a nasal 200 i.u. nasal spray available commercially.

Now, the primary endpoint CTX-I levels have been measured which corroborate the earlier findings. The nasal calcitonin positive control gave a fall in CTX-I, after 5 hours, of 60% of the starting value. In untreated subjects, diurnal variation causes a change of no more than 15% over this time period. However, Bone found that for all four of its oral formulations, the CTX-I concentration fell to exactly the same level as for the nasal calcitonin comparator, with no more than 10% variation either way. P values for the falls, for each group of seven patients, are all less than  $P < 0.05$ . Measurements over the five-day dosing period also show correspondence between nasal and test formulations.

These falls are very significant because it is on the basis of changes in CTX-I levels that the FDA will judge whether the formulation is bioequivalent to marketed products in the pivotal trial. "The data thus far obtained gives us confidence that we can design a pivotal trial which will meet the biological endpoints required. We also expect a very competitive and commercially viable dose and without using any New Chemical Entities," stated Mr Troels Jordansen, Managing Director of Bone Medical Limited.

"We will now prepare to revisit the FDA to determine the remaining pivotal programme under the 505(b)(2) strategy as discussed earlier with them."

Throughout normal adult life bone is in a constant state of breakdown and growth. In healthy individuals these two opposing forces are in equilibrium, but in osteoporosis, the balance has been lost and bone is progressively



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being broken down more rapidly than it can be repaired. Calcitonin is able to slow down this process since it is a natural hormone that acts directly on osteoclasts, the cells responsible for bone breakdown. One of the products of this breakdown is CTX-I (C-telopeptide collagen type I cross-linker) a fragment of the bone collagen matrix that appears in the bloodstream. The observation of a fall in CTX-I levels in the current study is a direct confirmation that the calcitonin has been delivered in a bioactive form that is acting upon the osteoclasts.

Calcitonin is a product that is only available in nasal or injectable form and has estimated worldwide sales in excess of \$US 500 million per annum.

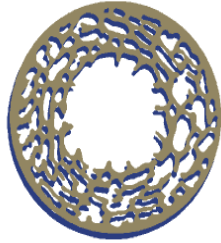
Apart from the impact on osteoclasts calcitonin also has been reported to have analgesic qualities for relief of bone pain. Patients for many years in southern Europe used the injectable form for these additional qualities.

Calcitonin, which is prescribed for lifetime, was approved by the FDA over 20 years ago and has a well established safety record which is a key advantage for long term chronic use. It is known to have slightly less impact on bone mineral density measures than the currently available alternative treatments (such as bisphosphonates and parathyroid hormone) but its safety record together with a capsule form is expected to improve compliance and lead to wider usage.

Recent literature reviews have also indicated the potential use of calcitonin for pain reduction and disease modification in osteoarthritis. The company will now be able to investigate this new and very significant indication as the result of these studies indicating that Bone's oral formulation is delivering calcitonin in a significantly biologically active way.

"Treatment of pain in osteoarthritis remains a challenge for physicians especially with increasing recognition that all anti-inflammatory agents, both newer COX-2 inhibitors and traditional non steroidal anti-inflammatory drugs, may have adverse cardiovascular effects in some patients. There is increasing interest in the use of calcitonin in osteoarthritis both for its pain relieving properties as well as potential effects on the underlying disease," said Professor Philip Sambrook from the Institute of Bone and Joint Research in Sydney.

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## **Investor Conference Call**

In order to answer questions from investors, Dr. New and Mr. Jordansen will host an investor conference call on Wednesday 1<sup>st</sup> August 2007 at 5pm Sydney time. The investor conference call is open to Australian based investors, for participation, please dial 1 800 672 949 and use access code 722 12132 2355#

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## **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
- Perthoxal™ oral parathyroid hormone
- bone cell regulators BN005 & BN008

### Arthritis

- TNF regulators BN006
- joint protection & collagen tolerance BN007