

AUSTRALIAN

# RESEARCH



## Contents

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# Bone Medical Limited (BNE)



Sector	Industry Group	Sub Industry	Disease Target
Healthcare	Biotechnology	Biopharmaceuticals	Osteoporosis & Arthritis

## Company Overview

Bone Medical was formed with the purpose of focusing on breakthrough treatments for bone and joint diseases and degeneration, in particular osteoporosis and arthritis. Its strategic goal is to be a leading international development based company in musculo-skeletal therapies by 2012. Bone Medical was formed in August 2004 with the acquisition of 80% of Bone Ltd by an ASX listed shell company, Revenir Ltd.

## Strategy

Bone's business model is essentially simple and can be described as follows:

- Outsourcing of non-essential functions;
- Minimisation of organisational overheads;
- Combine in-house development with academic collaborations to expand portfolio;
- Out-licence products at points of development to maximise shareholder return;
- Commitment to good corporate governance and scientific practices;
- Reserve certain co-promotional rights where appropriate to build a future specialist sales capability;

## Key Executives

### Dr James Phillips (CEO)

- International Pharmaceutical Executive with Novartis and Johnson & Johnson.
- Held senior roles in Business Development, Clinical Development & was a Novartis Business Unit Director.
- Led & accomplished MBO of Lifegard Technologies from J&J
- Medical Practitioner with MBA

### Dr Roger New (Chief Scientist)

- 30 years research and development in field of drug delivery
- World-recognised expert in liposomes: author of seminal reference book "Liposomes - A Practical Approach" published by OUP
- Devised three new systems for oral delivery of insulin, giving first positive human results ever observed in Type I diabetics
- Honorary professor at several foreign academic institutions. Consultant advisor to IRCD. Member of UK Govt Expert Mission on Biotechnology to China
- Patent applications filed and granted in areas of pharmaceuticals, diagnostics and microbiology

### John Fitzgerald (COO)

- Over 10 years experience in the pharmaceutical and biomedical industries.
- Honours degree in Science and an MBA
- Successfully worked in a diverse range of roles and functions including Product Management, IP, Business Development, and Marketing.
- In depth understanding of regulatory and subsidised pricing matters.
- Therapeutic area experience includes osteoporosis, rheumatoid and osteoarthritis, and anti-inflammatories.

## Key investment information

Market Cap: \$32.0M

### Capital Structure (M)

Ord shares on issue: 54.2  
Options (fully diluted): 1.0  
Convertible notes/other: n/a

Price as at 12-Nov: \$0.59  
12 month H/L: \$0.26 - \$0.80  
Avg daily turnover: \$0.02M  
Official listing date: Sep-04

### Substantial Shareholders

Proxima Concepts Ltd 74.0%  
Phoenix Hall Inwood Ltd 2.0%  
Rivertree 2.0%

### Cash Position

Cash (as at Sep-04): \$3.9M  
Years with planned expenditure: 1.25  
R&D as % expenditure: n/a

### Company contact



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Chief Executive Officer

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**www.bonemedical.com**

## Main Company R&D Projects – Major Technology & Market

### 1: BN002 Oral Calcitonin

Target Market: osteoporosis  
Stage: Phase II Human Clinical

Calcitonin has been on the market for over 25 years, only in injectable or nasal forms, and sells US\$700M per annum. BN002 oral calcitonin passed extensive pre-clinical testing, prior to the announcement in Sep-04 of positive phase I/IIa human clinical results, which showed that:

- Calcitonin was delivered to the blood stream and significantly reduced markers of bone destruction; and
- BN002 was well tolerated and no safety concerns arose.

BN002 contains no new chemical entities so its development program may be abridged if a bio-equivalence registration is accepted by regulatory authorities.

### 2: BN003 Oral Parathyroid Hormone (PTH)

Target Market: osteoporosis  
Stage: Phase I Human Clinical

Injectable PTH is the only product accepted by the US FDA to build bone and is predicted to sell >US\$450M annually by 2007. Three pre-clinical primate studies using BN003, undertaken by a major international pharmaceutical company, showed that BN003 delivered PTH into the bloodstream of tested animals and increased blood calcium levels as expected. BN003 oral PTH uses the same oral delivery technology as BN002, so the positive human clinical study bodes well for its success.

### 3: BN006 TNF Regulators

Target Market: rheumatoid arthritis  
Stage: pre-clinical

Tumour necrosis factor (TNF) is implicated as a cause of rheumatoid arthritis and injectable antibodies to negate its effect already sell US\$3.3 billion per annum. The BN006 TNF regulator programme has generated a new class of potential oral therapeutic compounds that may correct malfunctions of TNF production. Bone has entered into an agreement with the Institute of Bone and Joint Research in Sydney to test BN006 in animals. Testing is due to commence in Oct-04.

### 4: BN004; BN005/BN008; BN007

Target Market: Osteoporosis; Arthritis  
Stage: discovery

Bone has several additional projects in its pipeline at the discovery stage.

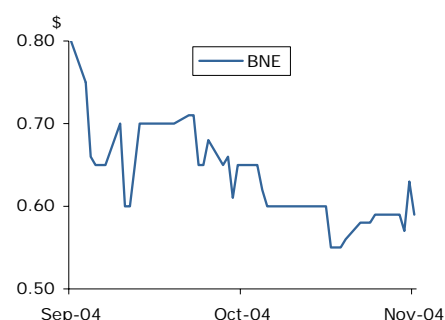
## Aegis Equities Comments

**Market Position:** BNE has exclusive rights to 3 drug development platform technologies that are used to generate products to treat bone and joint disorders. One improves oral delivery of peptide drugs (Acess™); another helps discover new drugs that regulate cell activity (Mozaic™); the third creates vaccines which can be given by mouth instead of injection (Vaccine™). BNE's strategy is to license out the 2 lead products and use up-front and milestone payments to fund development of earlier pipeline candidates.

**Milestone Record:** BNE backdoor listed in Aug-04 at which time it raised \$2.5M of new capital. Key milestones achieved since listing include: achieving a positive phase I/IIa trial for its oral calcitonin drug (BN002) for osteoporosis; identifying a new class of therapeutic agents as part of its BN006 program capable of restoring TNF levels in human cells (which may be useful in treating rheumatoid arthritis); and striking research collaborations with the Institute of Bone and Joint Research in Sydney.

**Risk Profile:** BNE key risks include cash reserves (cash should last to end CY05 or 1H CY06 but more cash will be needed from a licensing deal or capital raising for BNE to make license payments to its licensor); trial risks (although long use of the active agents in the two lead products as therapeutics moderates this risk) and control/liquidity risk (the largest shareholder owns 75% of BNE's stock and controls the licensor, Proxima Concepts). BNE's CEO is ex-Novartis and J&J, mitigating commercial risk.

Share price performance



Source: IRESS



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