



# Bone Medical

## ASX/MEDIA RELEASE

12<sup>th</sup> February 2007

### INVESTOR PRESENTATION

**Bone Medical Limited (ASX: BNE)** ("Bone Medical" or "the company") please find attached an investor presentation to be presented to existing and potential shareholders during the current week by the company's Chairman, Mr Paul Hopper and Director, Mr Leon Ivory.

- ENDS -

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### About Bone Medical Limited

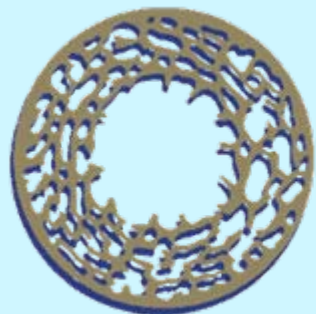
Bone Medical Limited is an international biopharmaceutical development company positioned to exploit the growing market in the treatment of bone disease particularly in osteoporosis and arthritis. Bone has a portfolio of biopharmaceutical development projects for the treatment of bone disease including,

#### Osteoporosis

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

#### Arthritis

- TNF regulators BN006
- joint protection & collagen tolerance BN007



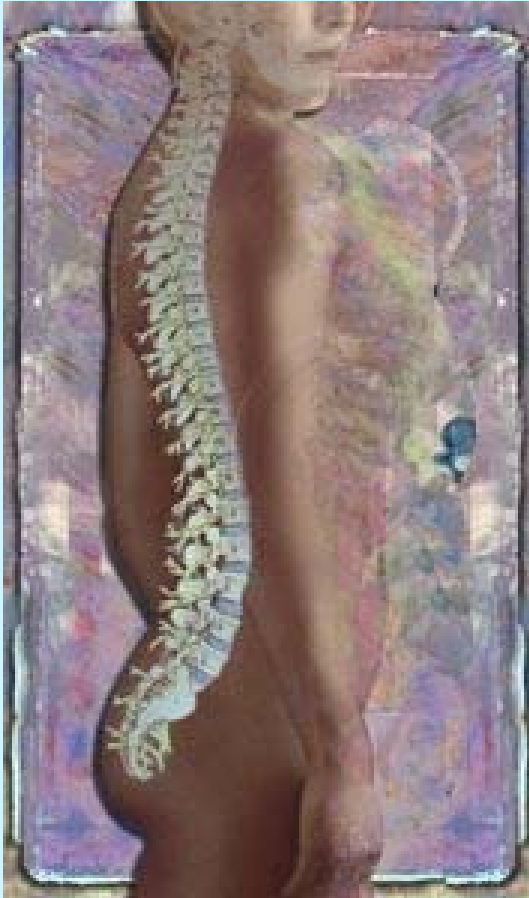
# Bone Medical



**Paul Hopper**  
Executive Chairman

**Feb 2007**

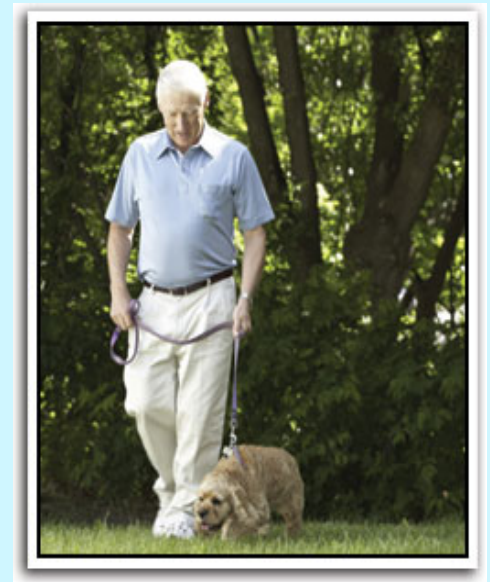
# Safe Harbour Statement



This presentation contains forward-looking statements that involve risks and uncertainties. These forward-looking statements are not guarantees of Bone Medical Limited's future performance and involve a number of risks and uncertainties that may cause actual results to differ materially from the results discussed in these statements. Factors that might cause the Company's results to differ materially from those expressed or implied by such forward-looking statements include but are not limited to, development and commercialisation of the Company's product portfolio; development or acquisition of additional products; and other risks and uncertainties. Bone Medical Limited undertakes no duty to update any of these forward-looking statements to confirm them to actual results.

- **Founded December 2002 - listed on Australian Stock Exchange**
- **Novel, proprietary oral drug delivery technology for musculoskeletal disease**
- **Phase I / 2a clinical trial for oral calcitonin- **Capsitonin™** - completed**
- **Phase I clinical study for oral parathyroid hormone- **Perthoxal™** completed**
- **Listed Public August 2004**
  - ✦ **Ticker: (ASX:BNE) (ADR:BMEDY.PK)**
  - ✦ **Office: Bentley, WA, Australia 6102**
  - ✦ **Shares Outstanding: 70,894,433 (Ordinary); 9,999,204 (Preferred C); 7,264,041 (Options)**
  - ✦ **Market Cap (Jan 2007): A\$xx million (20 cents per share)**
- **Over A\$5.5 million spent to date developing two core compounds**
- **Approximately A\$0.6 million cash on-hand**

- ✓ **Raised \$1.8m Nov 2006;**
- ✓ **Submitted Phase 2 oral sCT clinical trial protocol for Ethics approval in Qld;**
- ✓ **Submitted two Phase 1& 2 Study protocols for sCT & Perthoxal (PTH) for Ethics approval in Brazil;**
- ✓ **Research report by CCZ;**
- ✓ **Advanced pre-clinical animal studies on promising TNF down-regulator for rheumatoid arthritis in Germany & UK;**
- ✓ **Strengthened Board & management;**
- ✓ **Receipt of Australian Govt grants totaling A\$540K**
- ✓ **Growing focus on UK & Europe;**



- **Osteoporosis - sCT & PTH**
  - ✦ Approximately 200 million women worldwide
  - ✦ Incidence is expected to “double” in the next 50 years
  - ✦ Estimated US\$40 billion spent in USA and Europe
- **Osteoarthritis - sCT & TNF**
  - ✦ Over 20 million people in the U.S. alone
  - ✦ Most common form of arthritis, approximately 5-10% of population will develop



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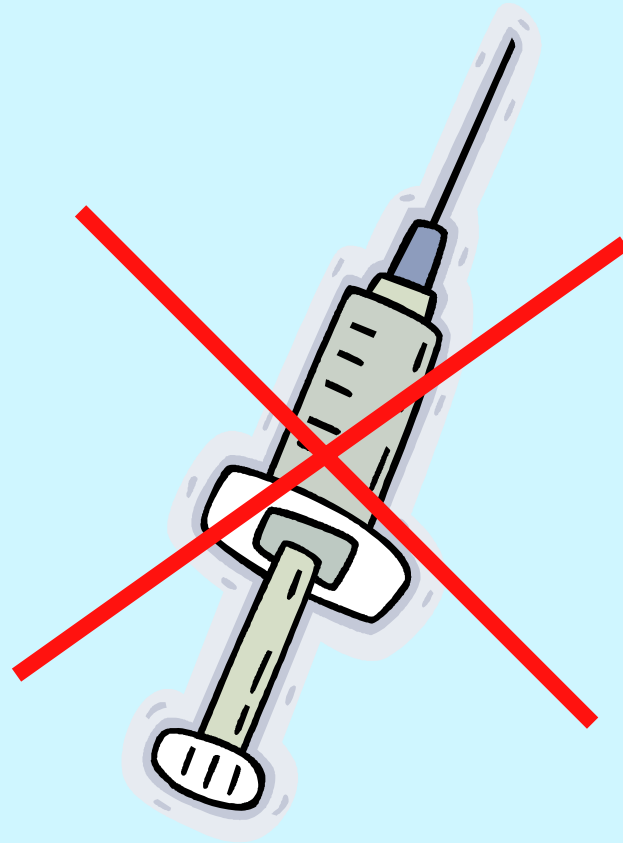
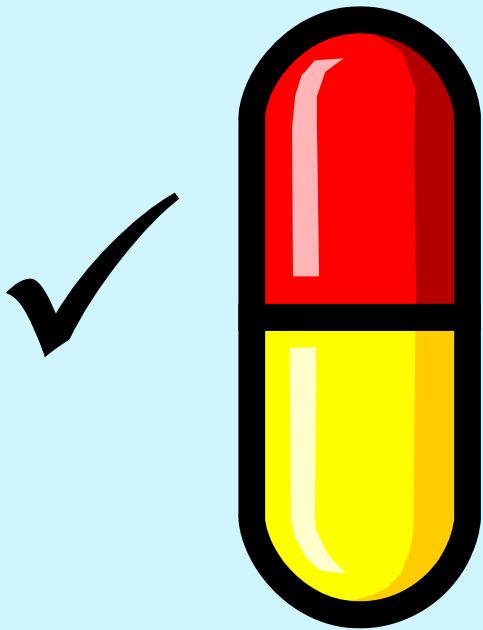
Sources: International Osteoporosis Foundation, CDC, Mayo Clinic, NIAMS, National Center for Chronic Disease Prevention and Health Promotion

# Competitor Drugs

PRODUCT	FORMULATON	THERAPEUTIC CLASS	SALES -US\$ 2005	MARKETER
Miacalcin	Inhaled	Calcitonin	\$275m	Novartis
Forteo	SQ Injection	Parathyroid Hormone	\$402m	Eli Lilly
Fosamax	Oral Tablet	Bisphosphonate	\$2,075m	Merck
Actonel	Oral Tablet	Bisphosphonate	\$1,058m	P&G
Evista	Oral Tablet	Estrogen Modulator	\$709m	Eli Lilly

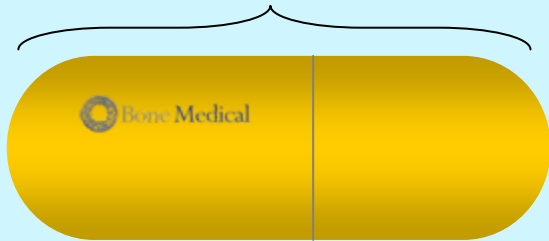


# BNE'S Advantage



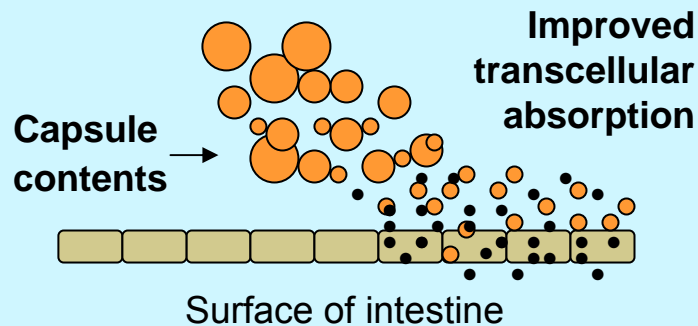
## Proprietary oral drug delivery technology

Enteric coating to protect against stomach acids



**Capsule Contents:**

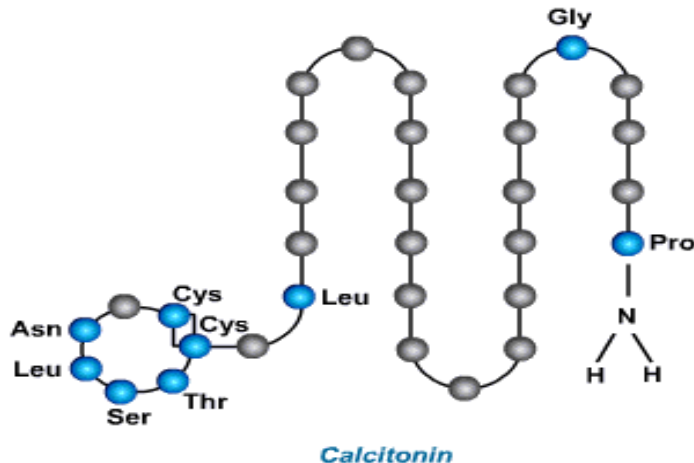
Drug, stabilizer, solubilizer,  
(GRAS pharmaceutical excipients)



- Formulated as a dry powder in an enteric coated capsule – simple and cheap to manufacture
- Capsule protects therapeutic peptides (sCT and PTH) from gastric degradation
- Capsule contents released in the jejunum in an area with neutral pH
- Technology utilizes existing approved substances – no NCE involvement
- Opportunity for rapid 505(b)(2) NDA submission

## Capsitonin™ *Oral Capsule* (synthetic salmon calcitonin peptide)

### Synthetic peptide of salmon calcitonin



*“Calcitonin has been used safely as a treatment for osteoporosis for over 30 years!”*

- Mechanism of Action:
  - ✦ Calcitonin aids in the maintenance of bone structure by interfering with osteoclast activity.
- Current Route of Administration
  - ✦ Nasal spray or injectible
- Use/Indication:
  - ✦ Osteoporosis
- Side Effects:
  - ✦ Mild joint ache, headache

- **Pre-IND minutes received Feb 2005**
- **Meeting focused on sCT as treatment for osteoporosis**
- **Bioequivalence development path and 505(b)(2) regulatory review process discussed**
- **Current Phase 2 trial will compare oral sCT with nasal spray (to demonstrate bioequivalence)**
- **Complete dose-ranging study & toxicology study**



- **This route permits companies to obtain FDA approval of new drug applications (NDAs) by relying, in part, on the FDA's findings for a previously approved drug;**
- **Examples of drugs which would fall under 505(b)(2) include changes in route of administration such as Bone's sCT & PTH, dosage & formulation, modified active ingredient, or new indication for previously approved drugs;**
- **Drugs appropriate for the 505(b)(2) pathway avoid lengthy, costly and in many cases, repetitive preclinical and clinical trials**



## Perthoxal™ Oral Capsule (synthetic parathyroid hormone peptide)

**Synthetic peptide  
of the human hormone**



*“The bone forming effects of parathyroid hormone have been known for 70 years!”*

- Mechanism of Action:
  - ✦ A controlling agent for maintaining normal calcium levels in the blood for strong formation of new bone.
- Route of Administration:
  - ✦ Injectable
- Use/Indication:
  - ✦ Osteoporosis
- Side Effects:
  - ✦ Some leg cramps, mild headache

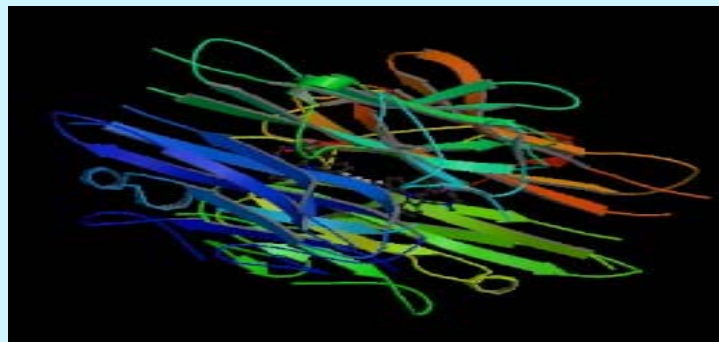
# Upcoming Clinical Trials

- **Capsitonin – Currently enrolling for Phase 2 repeat-dose, dose-ranging study in 35 subjects– Q-Pharm, Queensland**
- **Capsitonin – Ethics approval expected shortly for single-dose formulation & dosing study in 8 subjects; Q2 2007 – Brazil**
- **Perthoxal – Ethics approval expected shortly for single-dose formulation & dosing study in 8 subjects; Q1 2007 – Brazil**

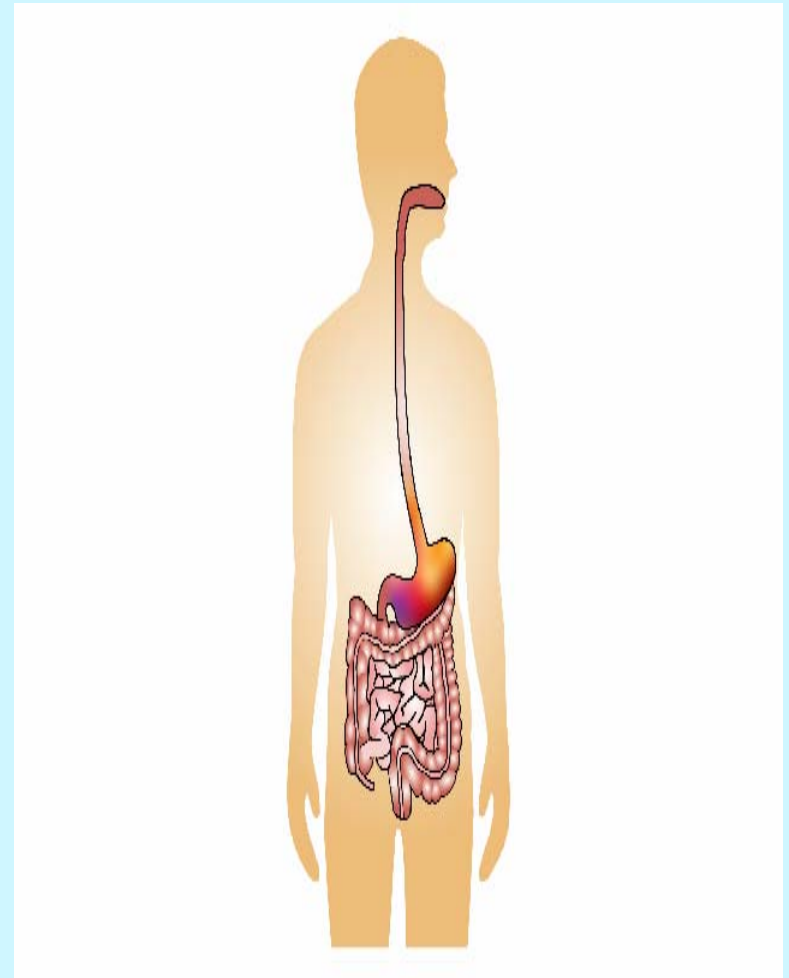


# TNF Down-Regulator- BN006

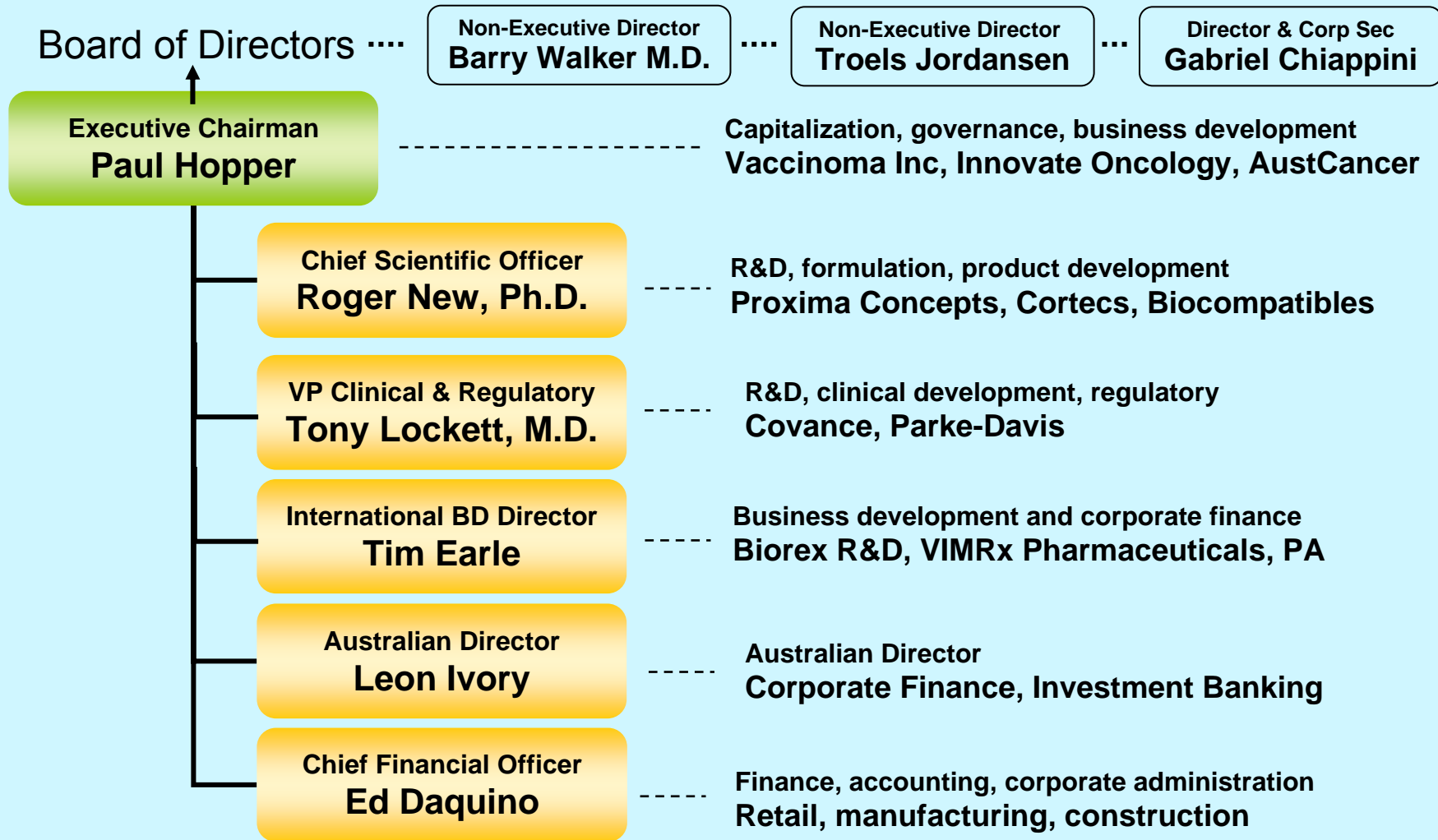
- **Potential treatment for rheumatoid arthritis (RA) – over-expression of TNF can destroy cartilage in RA**
- **Oligopeptide structured using a patented peptide scaffold**
- **Recent experiments carried out in Germany with BNE collaborator, Synovo, demonstrated ability to inhibit production of TNF in rat model, confirming earlier Australian results**
- **New collaboration announced with Kennedy Institute in London world leaders in anti TNF blockade**



- **Bone Medical has been granted exclusive worldwide rights to oral drug delivery technology in the field of musculoskeletal disease under three patent pending applications for each product:**
- **the use of aromatic alcohols to enhance the uptake of peptides across the small intestine;**
- **pharmaceutical compositions containing certain proportions of aromatic alcohols;**
- **and methods of solubilisation.**



# Key Management



1

**Outsource clinical development & manufacturing**

- **Minimal infrastructure cost and savings**
- **Corporate / management focus**

2

**Partner Capsitonin & Perthoxal (out-license and/or co-promotion)**

- **Rapidity to market and market up-take**
- **Minimize infrastructure build & capital needs**

3

**Selectively develop and out-license compounds in pipeline**

- **Broaden drug pipeline and product offerings**
- **Increase revenues and corporate growth**

# Why Bone Medical?

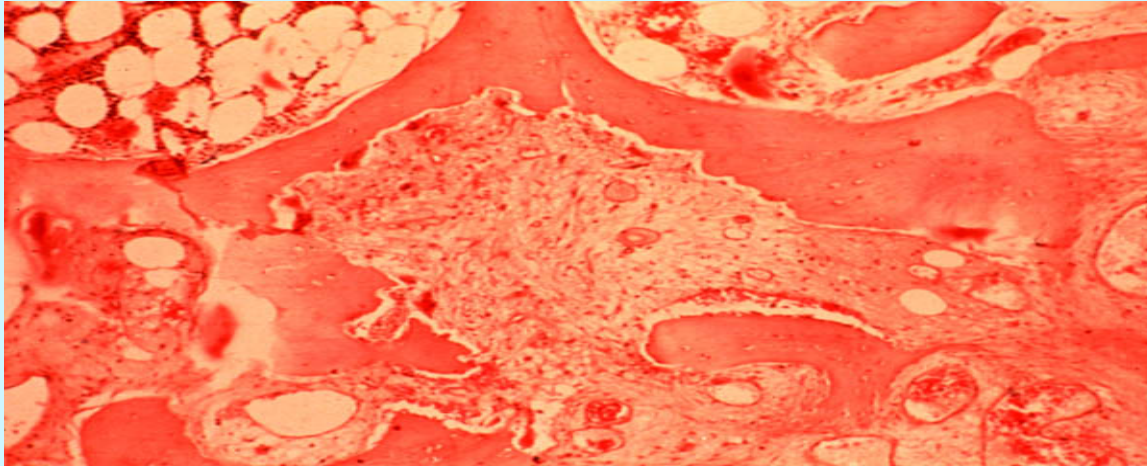
- ✓ **No molecule risk for sCt & PTH *-FDA APPROVED DRUGS***
- ✓ **Two products in clinical trials:**
- ✓ **Rapid regulatory process: potential bioequivalence &/or 505(b)(2) NDA submissions**
- ✓ **Multi-billion dollar market opportunity(s)**
- ✓ **Unique oral formulation technology with no NCE involvement**
- ✓ **Balanced portfolio between lower-risk drug delivery programs and potential breakthrough future treatments**
- ✓ **Experienced management driving low-cost business model**



# Year Ahead – Value Drivers



- ✓ **Complete Qld & Brazil trials for sCT**
- ✓ **End-of-Phase 2 meeting with FDA for sCT**
- ✓ **Complete Brazil trial for PTH**
- ✓ **Develop out-licensing discussions**
- ✓ **Submit further Govt grant applications**
- ✓ **Enhance SAC & management**
- ✓ **TNF down-regulator results from Kennedy institute, London (Imperial College)**
- ✓ **Appointment of Australian broker -CCZ- & build relationships with institutional investment community**
- ✓ **Value opportunity against US comparisons**



- **Proxima Concepts 61.4%**
- **Hall Phoenix 11.6%**
- **Piruniw Trustee 4.1%**
- **Top 20 shareholders own 88.74%**
- **Average monthly trading is 152,920 shares**

**Paul Hopper**

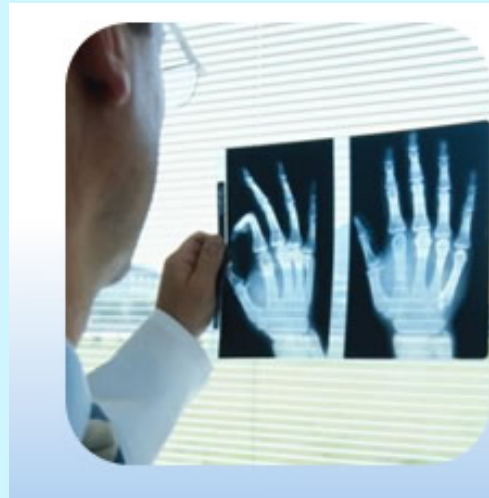
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