



**CHAIRMAN'S ADDRESS  
ANNUAL GENERAL MEETING  
30 NOVEMBER 2004**

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Thank you all for attending our Annual General Meeting. This is an opportunity for us to update you on our current status and developments and outline the immediate future as we see it.

We are delighted with the Company's progress since re-listing less than three months ago. Whilst newly listed, Bone Medical arrived fully formed. In particular, the recent success of our Phase II human study, is a substantial achievement for the company - the importance of which cannot be over-stated as it puts your company in the top few biotechs in this country who have positive human clinical data.

Additionally the delivery method proven with this positive human clinical outcome is to be used in our second project, which is about to enter clinical development.

The success our Company has enjoyed in such a short time is testament to the work completed by Proxima Concepts Limited, and then Bone Limited over the past five years and to the vision and dedication of Dr Roger New and Glen Travers over many more years than that. Indeed our Company is in the fortunate position of being able to apply the results of perhaps the last fifteen years of technical work done in this field of bone treatment.

The rapid clinical advances achieved has meant that we must review the future needs of the Company earlier than first anticipated. Because of this rapid clinical progress the Company has made and in particular with the positive result in a patient population, we as a Board believe it is time for and are in the process of seeking a dedicated full time Chief Executive who will be devoted to the capital markets ensuring the potential of our Company is fully understood in both Australia and the Northern Hemisphere. This person will also be responsible for taking the next steps required to elevate our Company to the next level of achieving its business plan. We expect this person will be located in the northern hemisphere thereby providing entrée into both the North American and European capital markets and biotech/pharmaceutical industry.

For family reasons, our current CEO, Dr Jim Phillips, whose services have been provided through our arrangement with Proxima Laboratories & Management Services, and who is based in Europe, will step down from that role at the end of the year. I, on behalf of the Board, would like to take this opportunity to thank Dr Phillips for his dedication, focus and energy in building first Bone Limited and then the creation of Bone Medical and setting us on the road to future success. I am also delighted to add that his services and expertise will not be lost to the Company as Dr Phillips has agreed to continue to support Bone's clinical studies and business development activities with international pharmaceutical companies. He will be retained as a "special advisor to the board of directors".

At this point I think it worthwhile to appreciate the milestones our Company has achieved as detailed in the various ASX Announcements released to date:

- **BN002 Clinical Trial Success (Osteoporosis)**

The first of Bone's human clinical studies was run at London's Atkinson Morley Hospital earlier this year investigating our oral calcitonin formulation BN002.

The trial, known as a bridging Phase I/IIa study, measured both safety & tolerability (Phase I) and efficacy (Phase II) parameters in the target clinical population (post-menopausal women).

The study demonstrated that BN002 oral calcitonin can be delivered orally and exert a statistically significant biological effect (Phase IIa component) as well as showing:

- Salmon calcitonin was measured in blood, although measurement was and is notoriously difficult;
- Blood levels of markers associated with bone breakdown were reduced bone destruction and expected; and
- Calcium levels in the blood were also reduced as expected

In July Bone announced the successful outcomes from the safety and tolerability component of the study (Phase I data). The study confirmed the safety and tolerability of BN002 in human subjects.

The outcome of the clinical study represents a major step forward for Bone in developing product for its commercialisation programme.

Calcitonin currently sells approximately A\$1 billion per annum, even though it has only been available as an injectable or in a limited number of countries as a nasal spray. It is hoped that the availability of an oral preparation will firstly convert the majority of current calcitonin users as well as grow the whole calcitonin market segment.

- **BN006 A New Class of Compounds for Rheumatoid Arthritis (Inflammatory Joint Destroying and Bone Diseases)**

Bone has uncovered a new class of oral therapeutic agents to potentially treat and/or prevent rheumatoid arthritis. This new class has shown the ability to restore the levels of tumour necrosis factor (TNF), which is implicated as the major cause of the destructive inflammation in rheumatoid arthritis, to normal in animal cell lines. Additionally initial toxicity tests have not shown any overt signs of adverse effects.

Pre-clinical work has already commenced at the Institute for Bone & Joint Research in Sydney. This proof-of-concept study will determine whether the first 2 of the 36 variants available to Bone can reduce the levels of TNF in animal models of inflammation. Assuming a positive outcome from this study the company will commence mechanism of action studies, which our discussions with Big Pharma to date have identified as being important for future licensing discussions.

The discovery of an entire new class of potential therapeutics is an uncommon event for any company and in this case one which could revolutionize the way rheumatoid arthritis is treated worldwide. This comes at a time where a product vacuum is being created for the treatment of arthritis from the global withdrawal of existing products due to safety concerns.

Currently there are three drugs on the market used to inhibit the effect of (TNF), a major element of inflammatory diseases, and all are administered via injection or infusion. Injectable products to treat rheumatoid arthritis by regulating TNF production have only been available for five years and already sales in 2003 totalled US\$3.3 billion and is predicted to grow to US\$11.5 billion by 2006!

- **BIF Grant Awarded to Bone Medical**

On 29 October, The Australian Federal Government announced that Bone had been awarded a Biotechnology Innovation Fund (BIF) grant of A\$250,000 for our BN003 oral parathyroid hormone (PTH) project.

The BIF is a competitive, merit-based program of the Australian Government aimed at helping biotechnology companies to move their projects beyond research stage and into early commercialisation. BIF helps companies reduce the cost of demonstrating proof-of-

concept of their project and may assist them to attract investment. In the scheme the Government provides matched funding for companies such as Bone.

The award of this non-dilutionary funding represents tremendous independent validation of our technology and represents another milestone achievement for the company.

The money will be used to fund a pre-clinical toxicity study and the first human clinical study using BN003 oral PTH. The toxicity study will be run at ICP Firefly, while the clinical study will be completed at the St Vincent's Clinical Trial Centre, both in Sydney. An ethics application should be submitted to St Vincent's Human Ethics Committee on 4 November and an outcome is expected towards the end of the month.

- **Institute of Bone and Joint Research Collaboration**

Bone has entered into a testing collaboration agreement with the Institute of Bone and Joint Research (IBJR) at the Royal North Shore Hospital, Sydney to examine the advancement of the company's products BN006 and BN007 for the treatment of rheumatoid arthritis.

The IBJR provides top of the line facilities for researchers advancing treatments for musculoskeletal degenerative diseases. The Institute is lead by Professor Philip Sambrook, the Florence & Cope Professor of Rheumatology at the University of Sydney and a member of the Editorial Boards of a number of international scientific journals. Professor Sambrook is also on the Board of Osteoporosis Australia and the NSW Committee of the WHO's Bone & Joint Decade as well as serving on the Asia Pacific League of Associations for Rheumatology (APLAR) and is Vice President of the Asia Pacific Osteoporosis Foundation.

As described above BN006 is a new class of orally available therapeutic compounds for the treatment of rheumatoid arthritis. Ethics approval has been received and testing of these has commenced in Sydney.

BN007 is a novel approach to the treatment of particular forms of rheumatoid arthritis. Rheumatoid arthritis is believed to be an auto-immune disease (self vs. self) and in certain forms one target of self attack is a protein called type II collagen (T2C), normally abundant in cartilage. The fundamental principle underlying BN007 is the oral delivery of amounts of T2C so that the immune system "recognizes" the substance (tolerance) and subsequently any inflammation is markedly down regulated.

- **Institute for Molecular Biosciences Collaboration**

Bone has also entered into a collaborative testing agreement with the Institute for Molecular Biosciences (IMB) at the University of Queensland to examine the advancement of the company's products BN005 and BN008 for the treatment of osteoporosis.

The IMB is affiliated with the Faculty of Health Sciences at the University of Queensland, which is lead by Executive Dean Prof Peter Brooks. Prof Brooks is a rheumatologist and is recognised internationally as an expert in the treatment and epidemiology of rheumatic diseases and has published widely. Prof Brooks is also the Chairman of the Australian Committee of the WHO's Bone & Joint Decade.

BN005 and BN008 are new projects to modulate bone breakdown and bone building via regulation of bone destroying and bone building cells called osteoclasts and osteoblasts respectively.

The development programme for BN005 has commenced on regulation of osteoblasts (involved in bone formation) and has already shown the ability to up and down regulate the activity of these bone cells. Early studies have shown activation of the osteoblast cells. The primary objective is to develop a library of oral drug candidates capable of building healthy strong bone, similar to parathyroid hormone, for the treatment of osteoporosis.

In contrast BN008 involves the development of a library of oral drug candidates capable of reducing the destruction of bone by osteoclasts. Osteoporosis is a condition whereby the normal destruction of bone by osteoclasts is not offset by a similar level of bone growth by osteoblasts leading to bone fragility and susceptibility to fracture. Osteoclasts are difficult cells to work with and the start of this project has been made possible by the collaboration with the IMB.

### **Capital Market Activity**

A challenge for any newly listed public company is that of appropriate recognition by the capital markets. Since re-listing in September this year, we have been active in introducing the Company to the stock market players. The Bone Medical story has been well received with several broking groups now taking time to closely look at the Company. We remain confident that as the understanding of the advanced stage of clinical progress is understood and capital market research on Bone Medical is completed, the Australian stock market will properly rate the value of your Company.

### **The Future**

The future is very exciting for Bone Medical. It is positioned ahead of a rapidly growing market in bone disease fuelled by the Baby Boomers and where there is substantial opportunity for new therapies. The Board believes that the products being developed by your company are innovative and have the potential to attend to the market needs.

In the coming year, a key theme will be the clinical programme, with two human trials currently being planned to commence in early 2005. The next Phase II human trial being planned will be done with a keen understanding of the FDA regulatory requirements as a fast track plan towards ultimate product registration.

Since further Phase II technical work is being undertaken in Sydney and Brisbane and a number of interested parties were also located in Sydney or Melbourne additional effort is being applied to provide an active presence in these locations. Our Chief Operating Officer Mr John Fitzgerald who has the responsibility of attending to these matters will continue to focus on assuring the development work and information is undertaken adequately in the appropriate location.

The Board will be exploring the opportunities offered in overseas capital markets and is taking advice from several parties in this regard. We are encouraged by the interest being shown in your Company in these capital markets.

The Company has adequate capital to continue doing the work required at the present time .

In conclusion, the Board of Bone Medical believes that your Company has made a tremendous start to its life as a publicly listed organisation, having achieved every milestone in its business plan to date.

The Board and staff are focused on developing product for the effective treatment of bone disease and believe that the Company is well positioned for future success both in terms of product/commercial outcomes and our primary objective of maximising shareholder value.

We welcome any questions you may have regarding the Company and its development.