

Bone Medical

ASX/MEDIA RELEASE

INVESTOR PRESENTATION

1 August 2007: Bone Medical Ltd (ASX:BNE) - please find attached an investor presentation to be presented to existing and potential shareholders during the current week by the company's Managing Director, Mr Troels Jordansen.

- 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

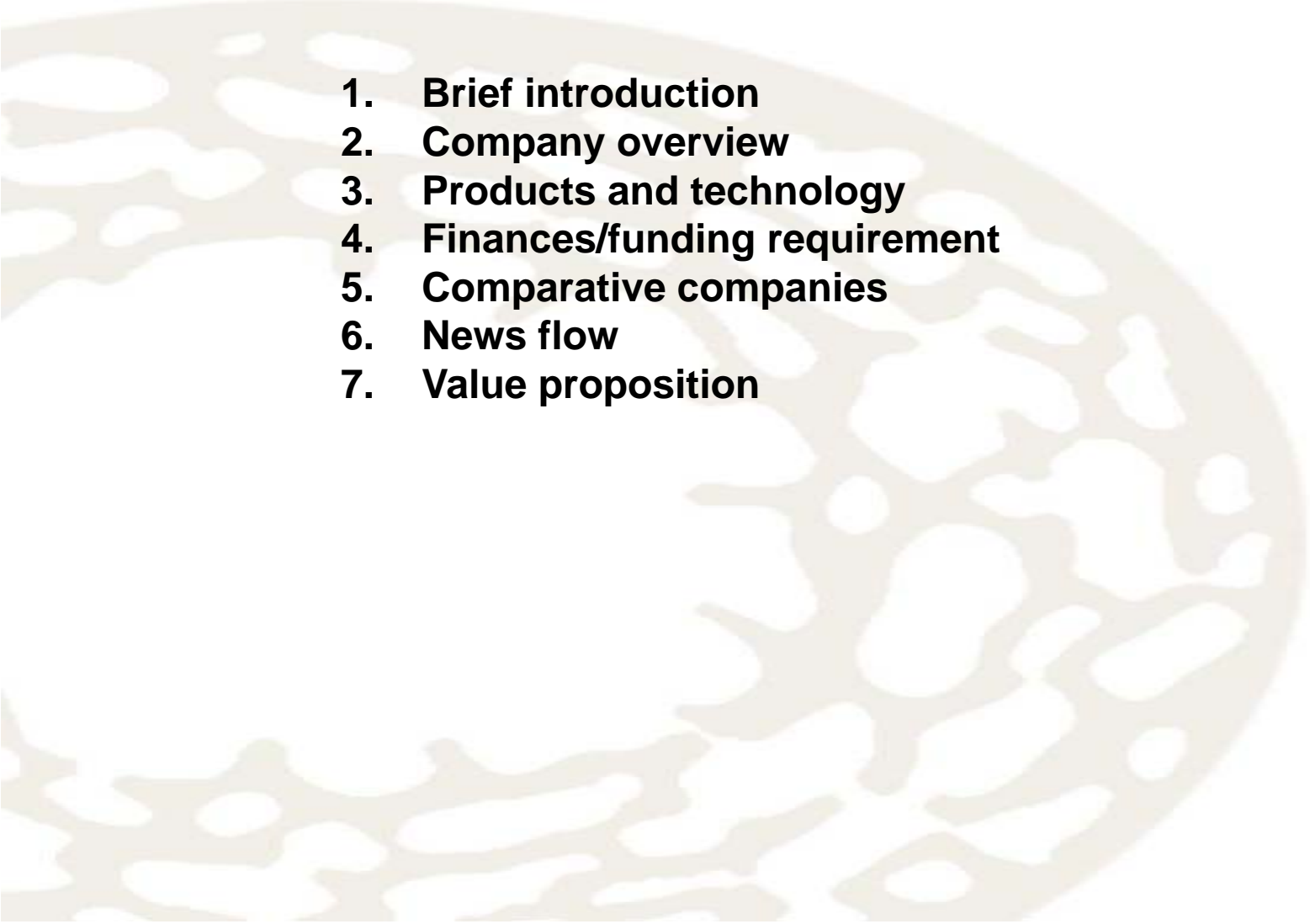
Arthritis

- TNF regulators BN006
- joint protection & collagen tolerance BN007



Bone Medical

Specialty pharmaceutical company
developing novel products for the
treatment of musculoskeletal
diseases

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- 1. Brief introduction**
 - 2. Company overview**
 - 3. Products and technology**
 - 4. Finances/funding requirement**
 - 5. Comparative companies**
 - 6. News flow**
 - 7. Value proposition**

Brief introduction

- Specialty pharma – single therapeutic area including Osteoporosis and Osteoarthritis: large market opportunities
- Multiple platforms generating strong and complementary product pipeline:
 - Drug delivery (Axxcess™)
 - Drug discovery (Mozaic™)
- Lead compounds use known API's – less risk
- Clear regulatory pathway – less expensive
- Products out of Phase IIa – corporate deals likely within 1-2 years
- Listed on ASX – corporate governance in place
- Virtual organisation – small burn rate
- Under-valued in comparison with peers – general upside

Company overview

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1. Brief introduction
 2. **Company overview**
 - I. **Business strategy**
 - II. **Market overview**
 - III. **Management**
 - IV. **Product pipeline**
 3. Products and technology
 4. Finances/funding requirement
 5. Comparative companies
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 7. Value proposition

Business strategy

- Keep virtual organisation and low burn rate
- Outsource all clinical development and manufacturing tasks
 - Retain corporate / management focus
 - Gain access to appropriate expertise
 - Avoid capital investment in development infrastructure
- Out-license
 - Work with established pharma partner targets
 - Maximize speed to market
 - Maximize market penetration
 - Maintain certain market rights
- Build therapeutic area franchise
 - Broaden product pipeline (in-license)
 - Increase revenues (out-license)

Market overview

- **Osteoporosis**

- Approximately 200 million women worldwide
- Ageing population in major pharmaceutical markets
- Incidence is expected to double in the next 50 years
- Bone fracture can lead to serious disability
- Estimated USD 48 billion spent to treat disease in North America and in Europe



- **Osteoarthritis**

- Around 6% (35 to 40 million) of the European population suffer from frequent knee pain and radiographic osteoarthritis.
- It is estimated that around 25% of the people with age 60 (40% over 70 years) and above suffer from disability due to osteoarthritis.

- **Target Treatments**

- Calcitonin (sCT): USD 4-500 million - nasal and injectable forms only (no oral form available)
- Parathyroid Hormone (PTH): USD 4-500 million - injectable form only (no oral form available)

Board of Directors

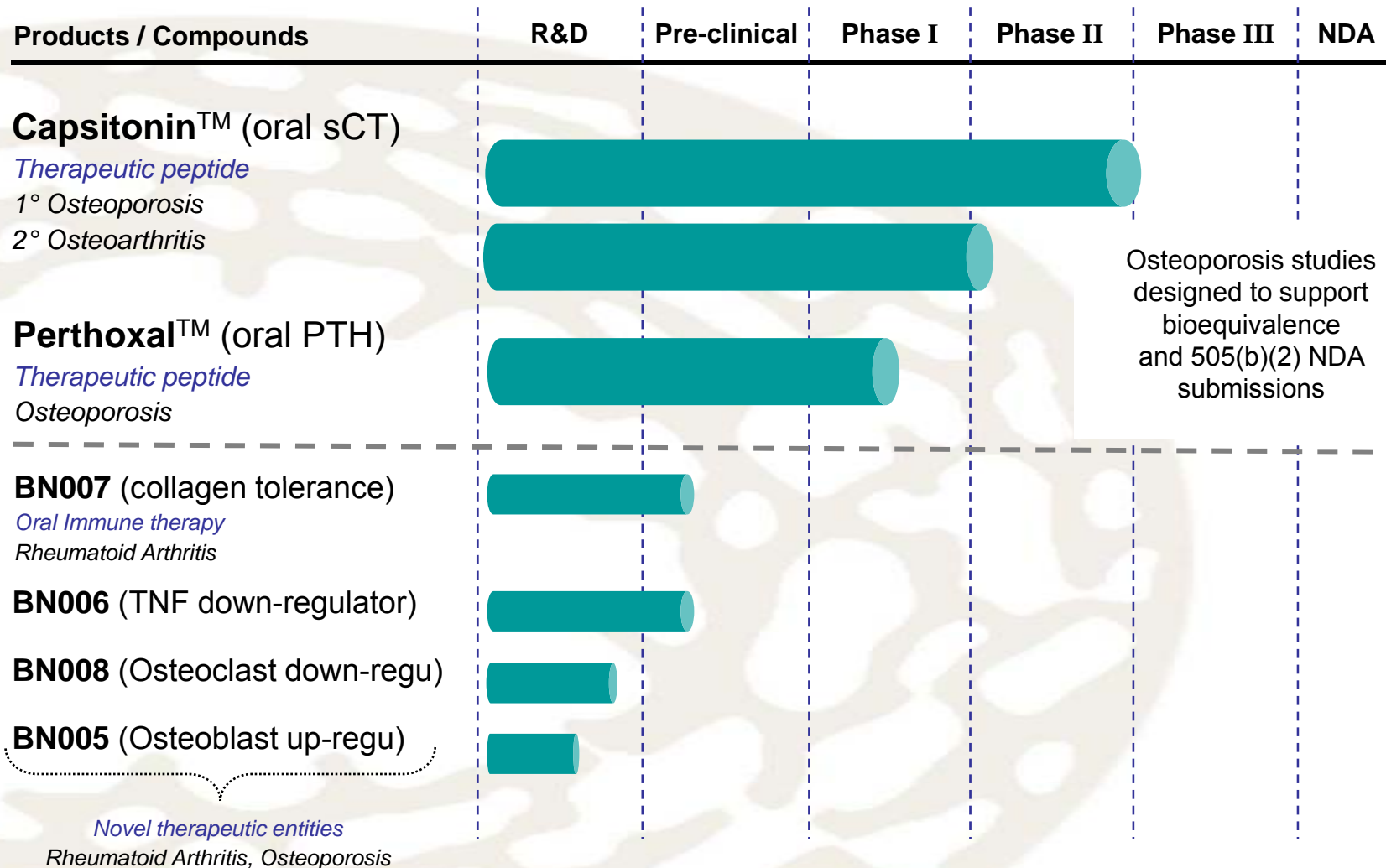
- Dr. Roger New, Chairman (United Kingdom)
- Leon Ivory, Director (Australia)
- Gabriel Chiappini, Director (Australia)
- Prof. Peter Brooks, Director (Australia)
- Dr. Barry Walker MD, Director (USA)
- Troels Jordansen, Managing Director (United Kingdom)

Management

- CEO, Troels Jordansen
- Chief Scientific Officer, Dr. Roger New Ph.D.*
- CFO, Ed Daquino
- VP Clinical and Regulatory, Dr. Tony Lockett MD*
- Australian Corporate Finance, Leon Ivory
- International BD Director, Tim Earle*

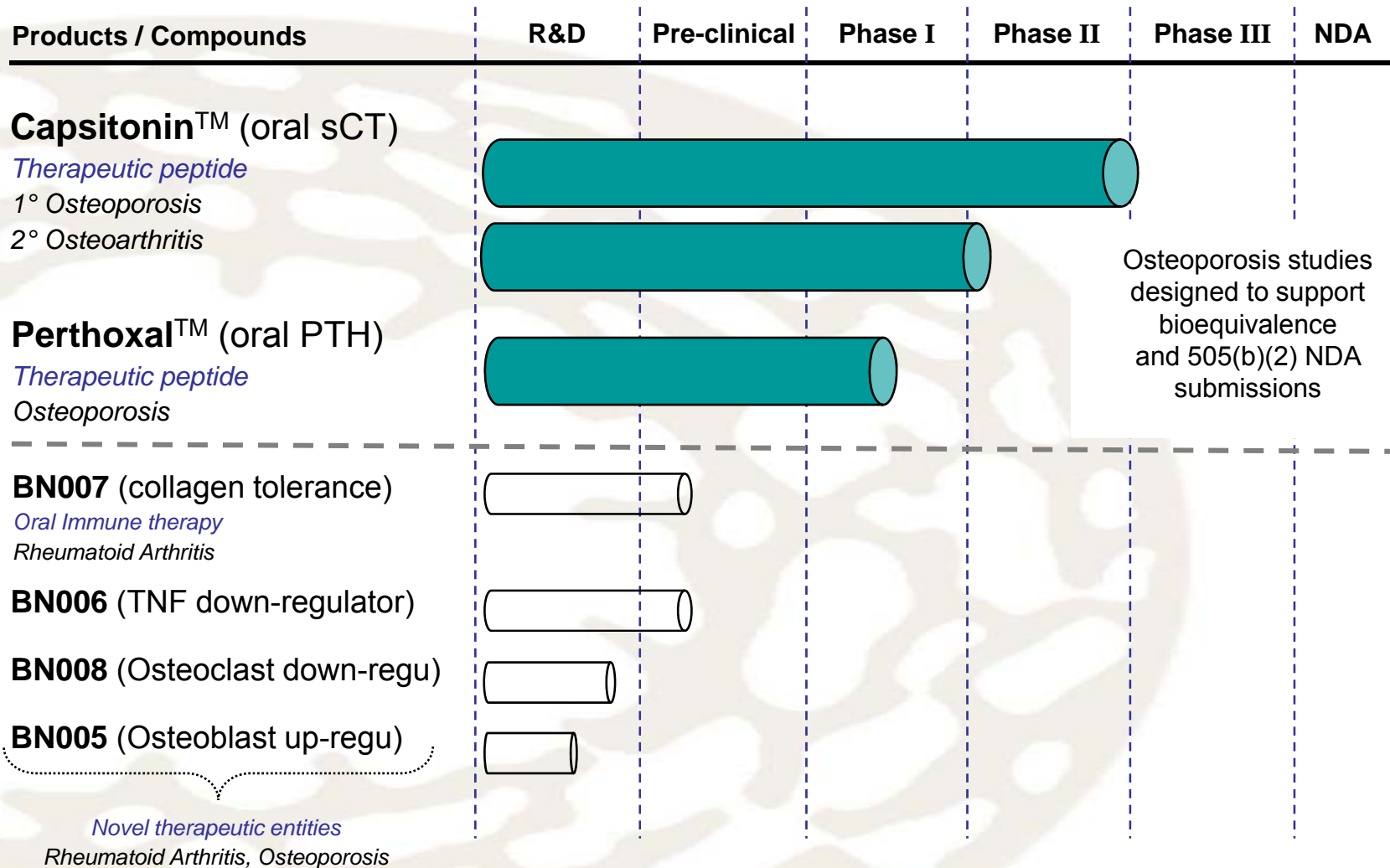
* Part time

Product pipeline



1. Brief introduction
2. Company overview
3. **Products and technology**
 - I. **Novel oral formulation**
 - II. **Lead compounds**
 - i. **Calcitonin**
 - ii. **PTH**
 - iii. **New products**
 - III. **Regulatory and IP**
4. Finances/funding requirement
5. Comparative companies
6. News flow
7. Value proposition

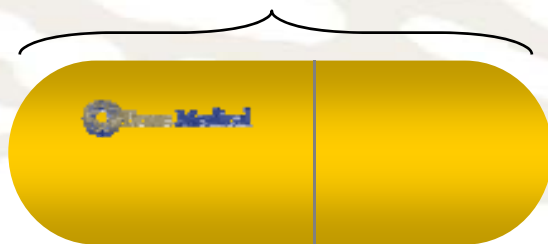
Access - Based products



Novel oral formulation

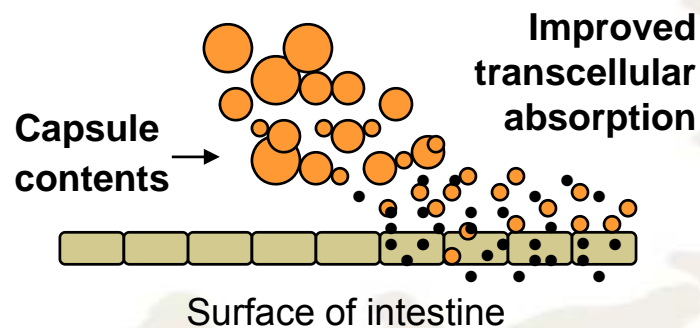
A_xess oral drug delivery technology

Enteric coating for easy swallowing



Capsule contents:

Drug, stabilizer, solubilizer,
(GRAS pharmaceutical excipients)



- GRAS / Pharmacopoeial excipients reduce toxicity concerns
- 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

Comparison of oral delivery technologies

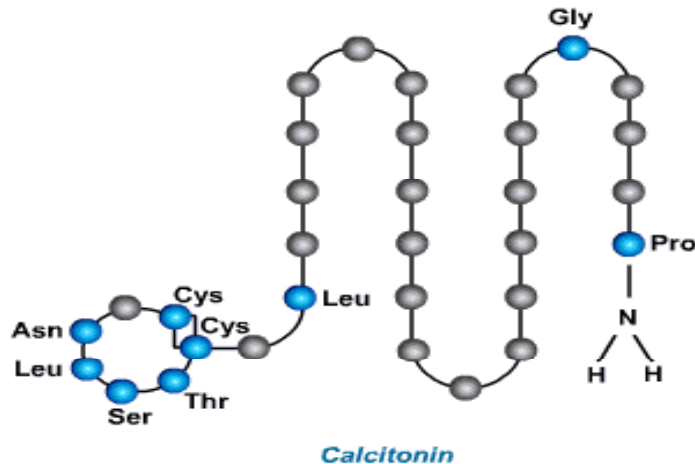
	Unigene	Emisphere	Nobex (BioCon)	Bone Medical
Absorption mechanism	Opening of tight junctions	? Through the cell membrane	Unknown	? Through the cell membrane
Delivery vehicle	Capsule / Tablet	Tablet	Tablet	Capsule
Non-NCE	Yes	No	No	Yes
GRAS / pharmacopoeial	No	No	No	Yes
Eligibility for 505(b)(2)	Unknown	Unlikely	No	Yes
Stage of development	Phase II	Phase III	Phase I	Phase II
Estimated bioequivalence	Very low (<5%)	Low (<5%)	?	Moderate – high (up to 10%)

Based on publicly available information

1st lead product - Capsitonin™

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. Osteoarthritis may be the next indication.”

- Mechanism of action:
 - Calcitonin aids in the maintenance of bone structure by interfering with osteoclast activity
- Current route of administration
 - Nasal spray or injectable
- Use/indication:
 - Osteoporosis, Osteoarthritis
- Side effects:
 - Mild joint ache, headache

Capsitonin™ - Phase I/IIa

Background

- Existing injectable and nasal formulations of calcitonin are difficult to administer affecting patient compliance and limiting its use as a treatment option
 - More than 50% of patients withdrew from nasal study
- To date, no oral formulation of calcitonin has been brought to market

Phase I/IIa

- Open label safety & tolerability and preliminary efficacy / activity
- Undertaken at St. Georges Hospital, London in 2004

Study design

- 8 post-menopausal, female volunteers
- Sequential, cross-over design
 - Positive control (Miacalcin™ nasal spray) – active comparator
 - 1,250 i.u. Capsitonin™
 - 2,500 i.u. Capsitonin™
- Measurement of key biomarkers: serum calcitonin, serum CTX, and blood calcium

Results

- Encouraging for both strengths, but capsule delivery expected to be better

Capsitonin™ – Phase IIb

- Dose finding clinical trial
- Open label with 5 arms, repeat dose against control (Miacalcin™ Nasal Spray)
- Undertaken at Q-Pharm, Brisbane, Australia

Study design

- 35 post-menopausal, female volunteers
- Randomized and parallel design
 - Positive control (Miacalcin™ nasal spray) – active comparator
 - 1,250 i.u. Capsitonin™ Axcress™ III
 - 2,500 i.u. Capsitonin™ Axcress™ III
 - 1,250 i.u. Capsitonin™ Axcress™ IV
 - 2,500 i.u. Capsitonin™ Axcress™ IV
- Measurement of key biomarkers: CTX and adverse events, calcium and phosphate levels blood calcium

Capsitonin™ – Phase IIb

Results

Calcium levels

- All four Capsitonin™ formulations showed significant reduction on calcium levels and biological effect
- Two formulations were within +/- 10% variation from Nasal Spray comparator, hence showing equivalent activity in FDA terminology

CTX1 - biomarker

- After 5 hours, 60% reduction from starting point equal to that of Nasal Spray comparator
- No treatment group showed only 15% reduction
- All 4 Bone formulations reduced CTX levels to the same point (+/- 10%)
- For all Bone formulations $P < 0.05$
- Bioequivalence to FDA approved Nasal Spray demonstrated

2nd lead product - Perthoxal™

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

Study Objective

- **Phase 1 open label safety & tolerability study and preliminary pharmacodynamic effects**

Study Design

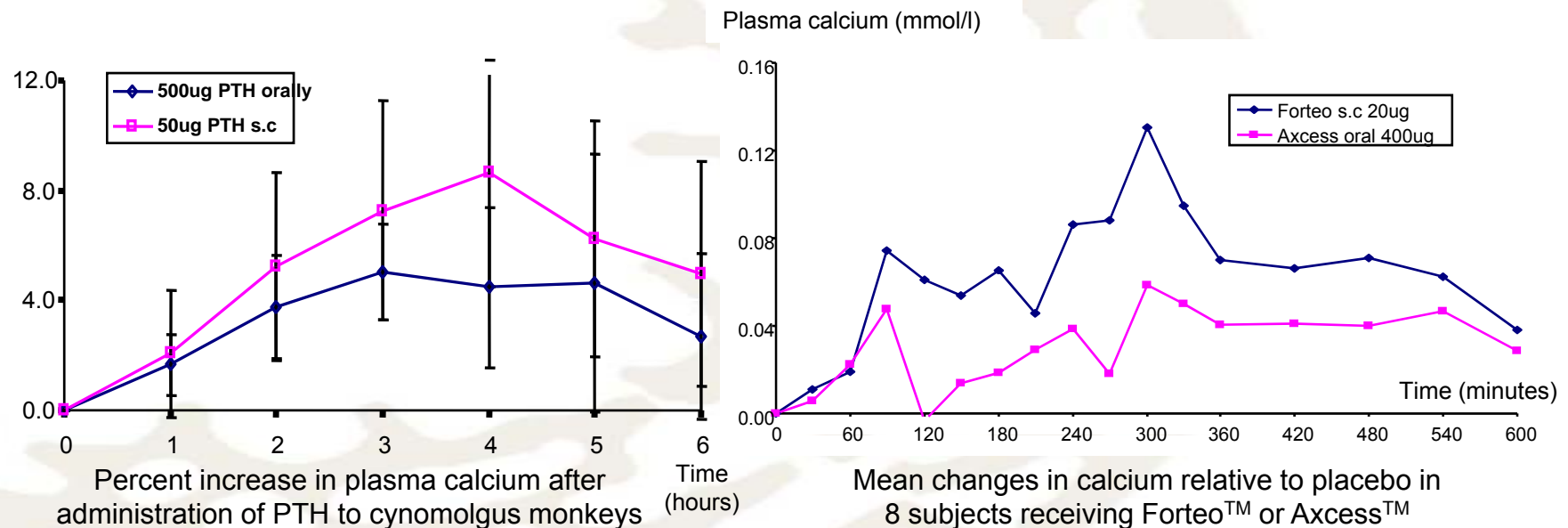
- **18 post-menopausal, female volunteers**
- **Sequential, cross-over design (12 of 18 patients only) of two different formulations of Perthoxal™**
 - Positive control (s.c. injected PTH) – active comparator
 - Axcross™ III 400ug Perthoxal™
 - Axcross™ IV 400ug Perthoxal™
- **Measurement of key biomarker: serum calcium concentration**

- **Background**

- Existing injectable formulation of parathyroid hormone (PTH) is difficult to administer affecting patient compliance and limiting its use as a treatment option
- To date, no oral formulation of PTH has been brought to market

- **Perthoxal™**

- Encouraging pre-clinical and clinical data



Perthoxal™ - Phase II

Study Objective

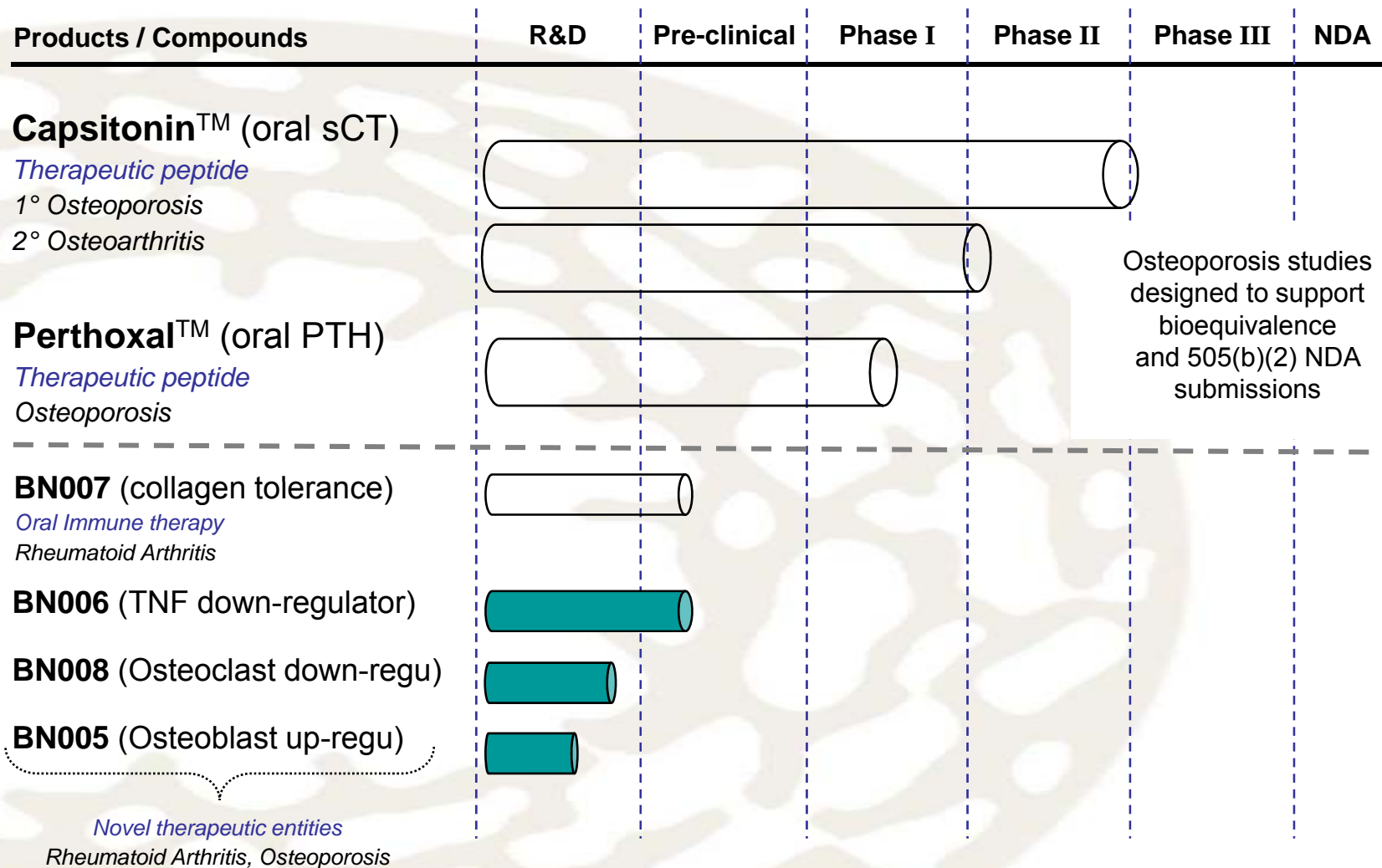
- Formulation finding cross-over study

Study Design

- 8 post-menopausal, female volunteers
- Single, blind, cross-over design of two different formulations of Perthoxal™
 - Axxcess™ IV 400ug Perthoxal™
 - Axxcess™ III 800ug Perthoxal™
- Measurement of calcium level and fragments of PTH
- Q-Pharm, Brisbane, Australia

Ethical committee approval expected August 2007

Mozaic-based products



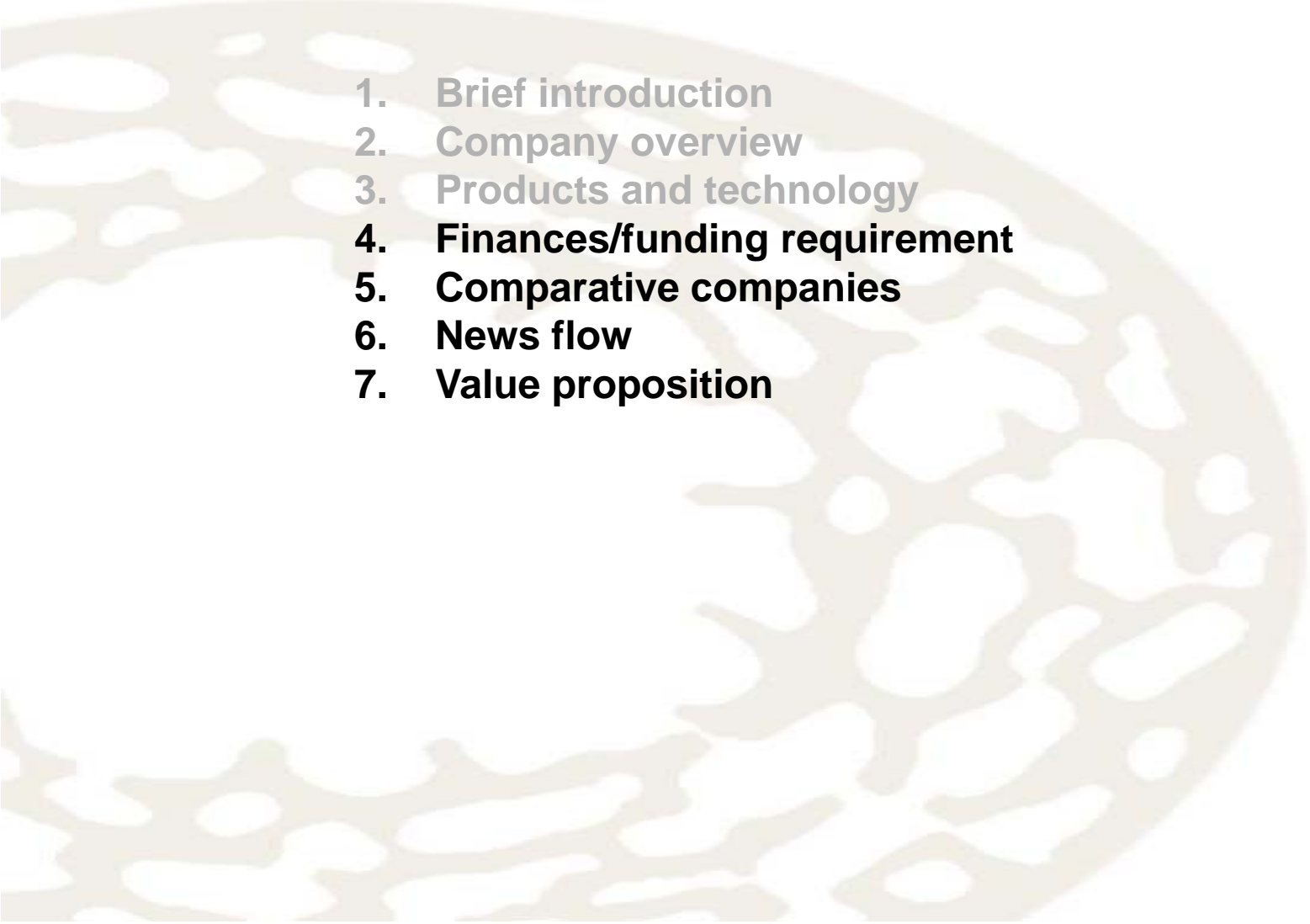
Regulatory

- Pre-IND meeting with FDA (12/05) supported proposed Capsitonin™ clinical development plan for Osteoporosis and submission of NDA under 505(b)(2) procedure
- Successful conclusion of Phase 2 repeat-dose, dose-ranging PD study to select doses for pivotal
- Pivotal study; 6-month study with bioequivalence to nasal calcitonin (1H 2008)
- Potential for relatively rapid filing of NDA - 2008

IP

- Bone Medical has been granted exclusive worldwide rights in the field of musculoskeletal diseases to the following patents and patent applications:
- **Axcess™**
 - Axcess™ 1 – class I absorption enhancers; filed 10/00*, approved in Europe
 - Axcess™ 2 – class II absorption enhancers; filed 4/03*
 - Axcess™ 3 – combination of absorption enhancers; filed 4/03*
 - Axcess™ 4 – novel formulations; filed 2/06
- **Vaccine™**
 - Vaccine™ 1 – immunogenic compositions; filed 11/94, granted in Europe
 - Vaccine™ 2 – immunogenic compositions; filed 8/94, granted in US
- **Mozaic™**
 - Mozaic™ 1 – creation of epitopes; filed 6/99*

(* - in international application phase)

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Finance and funding requirements

Finance

- Listed in August 2004
 - Ticker: (ASX:BNE)
 - Office: Bentley, WA, Australia 6102
 - Shares Outstanding: 76,331,024 (ord.); 9,999,204 (pref. C); 7,112,591(options)
 - Market Cap (26.07.07): AUD 27.5 million / USD 23.9 million / GBP 11.7 million
 - Average monthly cash: AUD 240,000 / USD 200,000 / GBP 100,000
 - Cash in bank (June): AUD 1.5 million / USD 1.3 million / GBP 643,000

Funds use

- Capsitonin™ - Osteoporosis - initiate Phase III/pivotal study
- Capsitonin™ – Osteoarthritis – FDA meeting and Phase II
- Toxicology study in rats (1 month)
- Perthoxal™ – Phase IIa repeat dose study
- Progress additional targets towards clinical development
- Step up licensing discussions

Comparative Companies

Company	Musculoskeletal products Approved or in clinical development	Market capitalisation
Bone Medical Ltd. Perth, Australia (ASX)	Oral sCT – Phase 2/3 Oral PTH – Phase 2	USD 24 million
Emisphere, Inc. Tarrytown, NY (NASDAQ)	Oral sCT – Phase 3 (partnered with Novartis) Oral PTH – Phase 1 (partnered with Novartis) <i>(Plus products in other therapeutic areas)</i>	USD 120 million
Nastech Pharmaceutical Co. Inc. Bothell, WA (NASDAQ)	Nasal sCT – Approved for sale (partnered with Par) Nasal PTH – Phase 2 (partnered with P&G) <i>(Plus products in other therapeutic areas)</i>	USD 120 million
NPS Pharmaceuticals, Inc. Salt Lake City, UT (NASDAQ)	Oral cinacalcet – Approved for sale (partnered with Amgen) Injectable PTH – Approved in Europe (partnered with Nycomed); awaiting approval in US Oral calcilytics – Phase 1 (partnered with GSK) <i>(Plus products in other therapeutic areas)</i>	USD 217 million
Unigene Laboratories, Inc. Fairfield, NJ (NASDAQ)	Injectable sCT – Approved for sale Nasal sCT – Approved for sale (partnered with Upsher Smith) Oral sCT – Phase 2 Oral PTH – Phase 1 (partnered with GSK)	USD 189 million

Competitive activity

Osteoporosis

- Novartis and Emisphere
- Oral salmon calcitonin in Phase III
- Three year study
- Randomized, multi-centre, placebo-controlled study to evaluate the safety and efficacy of oral calcitonin candidate for osteoporosis
- More than 4,500 osteoporosis patients
- Multi-centre study in Europe, United States, China and Latin America

Competitive activity

Osteoarthritis

- Novartis and Emisphere
- Oral salmon calcitonin in Phase III
- Two year study ^[1]
- A Randomized, Double-Blind, Multi-Center, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oral Salmon Calcitonin in the Treatment of Subjects With Knee Osteoarthritis ^[1]
- Primary: X-ray, pain and WOMAC (disability) ^[1]
- Secondary: Biomarkers, x-ray, MRI and adverse events ^[1]
- More than 2,000 osteoarthritis patients ^[2]
- Multi-centre study in Europe and United States ^[2]

Sources:

[1] ClinicalTrials.gov (2007) Efficacy and Safety of Oral Salmon Calcitonin in Patients With Knee Osteoarthritis. Available from: <http://www.clinicaltrials.gov/ct/show/NCT00486434?order=1>. Accessed: June 15, 2007.

[2] Emisphere Inc. (2007) Press release: 'Emisphere Announces Initiation of Phase III Clinical Program of Oral Calcitonin for the Treatment of Osteoarthritis'

Value proposition

- Two products in clinical trials:
 - **Capsitonin™** - oral calcitonin for osteoporosis *and* osteoarthritis
 - **Perthoxal™** - oral parathyroid hormone for osteoporosis
- Rapid regulatory process: potential bioequivalence and/or 505(b)(2) NDA submissions
- Multi-billion dollar market opportunity(s)
- Unique oral formulation technology with no NCE involvement
- Novel therapeutic entity discovery platform with proven potential
- Balanced portfolio between lower-risk drug delivery programs and potential breakthrough future treatments
- Experienced management driving low-cost business model



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