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# Mesoblast's Key Product Franchises Featured at Nomura Asia Equity Forum

**Melbourne, Australia; 14 June 2011:** Global regenerative medicine company, Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY), was featured today at the 8<sup>th</sup> Nomura Asia Equity Forum being held in Singapore. Mesoblast was the only Australian company to present at the respected Asian investor forum.

Investors were provided with clinical and commercial updates on Mesoblast's advances using its proprietary adult stem cell technology platform. Of particular focus was the progress in Mesoblast's three key product franchises for cardiovascular, spinal orthopedic, and inflammatory conditions, as well as the company's timely progression towards a Phase 3 clinical trial of its product for augmenting bone marrow transplantation in cancer patients.

Mesoblast highlighted the massive revenue potential of its cardiovascular product franchise. The outstanding Phase 2 results of Revascor<sup>™</sup> in congestive heart failure were featured, as well as recent mechanistic data showing that the product improves blood flow in ischemic heart muscle. Together, these results underscore the potential of Revascor<sup>™</sup> for the treatment of congestive heart failure, acute myocardial infarction, chronic refractory angina, and an increasing population of patients with vascular heart disease.

The investor forum was updated on Mesoblast's spinal orthopedic franchise targeting multiple conditions with major unmet clinical need. Investors were told that a Phase 2 trial for repair of degenerating intervertebral discs was due to commence shortly, and that the cervical and lumbar fusion Phase 2 clinical trials remain on track.

Finally, the company provided investors with strategic focus on a new intravenously delivered product franchise for a range of inflammatory conditions such as diabetes, lung disorders, and joint conditions, as well as inflammatory neurological conditions such as Multiple Sclerosis.

Below is a copy of the slide presentation.



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#### **About Mesoblast Limited**

Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY) is a world leader in the development, manufacture, and commercialization of biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights to a series of patents and technologies developed over more than 10 years relating to the identification, extraction, culture and uses of adult Mesenchymal Precursor Cells (MPCs). More information – <a href="https://www.mesoblast.com">www.mesoblast.com</a>

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# mesoblast the regenerative medicine company



8th Nomura Asia Equity Forum 14 June 2011

# **Forward looking statements**

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation, including any comments made during or following the presentation, may contain forward-looking statements that are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationship with Cephalon and future benefits of that relationship; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Factors and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forwardlooking statements.



# **Investment snapshot**

Mesoblast is a public company, listed on the Australia

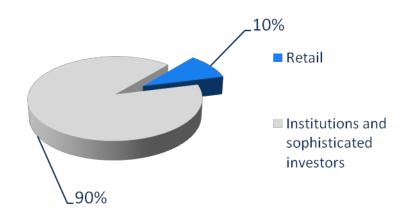
It is inclu

lian Securities Exchange since 2004.	Current share price	A\$8.60
cluded in the S&P/ASX 200 Index.	Cash available (approx)	A\$270m
	Market capitalization	A\$2,400m

**Issued shares** 

Capital raisings	A\$m
IPO @ 50 cents	21.0
Equity placements	
Jul-06	17.4
Dec-07	13.4
Apr-09	10.8
May-10, 2 <sup>nd</sup> tranche Sep/Dec-10	35.8
Options & US raisings	18.2
Cephalon equity investment	106.8
Total funds raised	223.4

#### Mesoblast ownership





279m

#### Our proprietary adult stem cells

- potent, purified adult mesenchymal precursor cells
  - strong safety profile no immune reactions
  - avoid ethical and safety issues associated with embryonic stem cells
  - backed by strong patent position
- "off the shelf" just like classic pharmaceutical drugs
  - batch to batch consistency
  - clear, rapid regulatory pathway
- easy to expand in large numbers
  - low cost of goods, no supply constraints
  - high margin business model



#### The Mesoblast value proposition – the three pillars

#### 1. The Cephalon alliance

- delivers proven execution capability in major global markets
- drives clinical programs in key therapeutic areas experienced team
- cash from milestone payments to fund Mesoblast pipeline

#### 2. Orthopedic pipeline

- intervertebral disc repair
- stress fractures
- spinal fusion

#### 3. Intravenous product pipeline

- systemically delivered cells
  - diabetes
  - immunologic conditions (eg rheumatoid arthritis)
  - inflammatory diseases of various tissues (eg lungs)

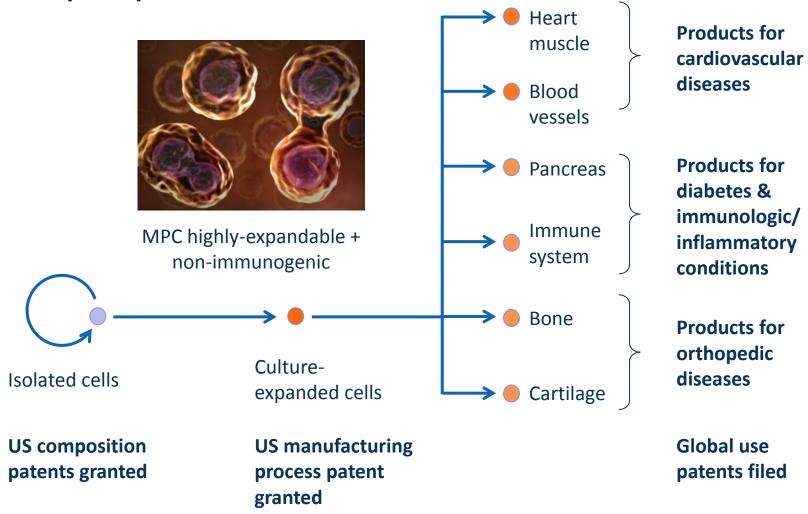


#### Cephalon strategic alliance

- Cephalon received exclusive worldwide commercialization rights to selected
   Mesoblast products in cardiovascular and neurologic indications, and bone marrow transplantation
- Cephalon responsible for funding Phase 3 clinical development
- Mesoblast receives upfront fee of US\$130 million, plus up to US\$1.7 billion in milestone payments, plus revenue split
- Cephalon acquired 19.99% stake in Mesoblast
- Mesoblast cash balance of \$270 million to fund other major indications including
  - diabetes
  - immunologic conditions (eg rheumatoid arthritis)
  - inflammatory diseases of various tissues (eg lungs)
  - ophthalmic indications
  - orthopedic cartilage and bone conditions
- Mesoblast retains all manufacturing rights

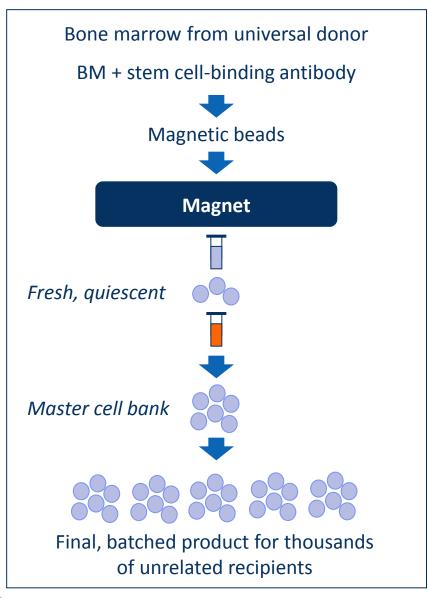


# We own the intellectual property on Mesenchymal Precursor Cells (MPC)





### Our industrial scale manufacturing process



- homogeneous cell population
- well-controlled cell expansion
- efficient large-scale expansion
- lower costs of cell culture process
- batch-to-batch consistency
- stringent release criteria
- greater potency of expanded product



### Manufacturing strategy is central to maximising value

#### 1. State-of-the-art manufacturing plant via strategic alliance

- cost neutral
- tax effective geographical location
- best of breed, cutting edge technology

#### 2. Retain control of manufacture for all products

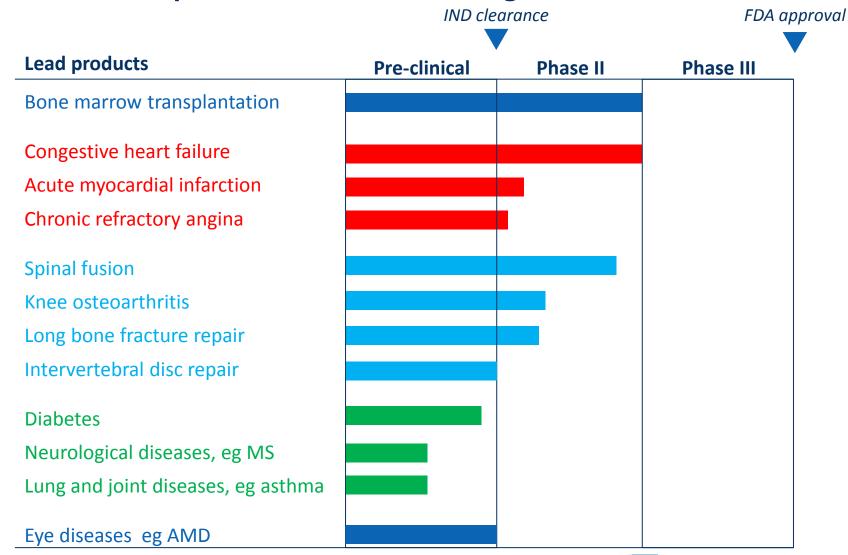
- product delineation for distribution partners
- maintain optimal product pricing differences

#### 3. Commercial benefits

- reduced COGS, increased margins
- R&D support for new product pipelines
- leverage new technologies



## "Off-the-shelf" product franchises driving value creation





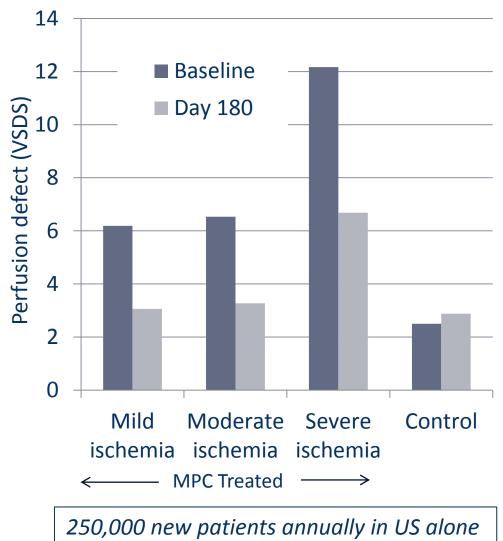
## Cardiovascular franchise – congestive heart failure (CHF)

- 60 patient multi-center, randomized, controlled Phase 2 trial
- Class II-IV CHF, ejection fraction < 40% (high 6- and 12-month mortality)</li>
- randomized 3:1 controls to MPCs at 25M, 75M or 150M cell doses
- cells injected by J&J NOGA Myostar™ catheter single injection
- primary endpoint of safety met, no adverse events associated with MPCs at any dose
- key efficacy endpoints after average 18 month follow-up:
  - 50% reduction in serious adverse cardiac events (p=0.001)
  - 80% reduction in major adverse cardiac events (p=0.005)
  - 13% cardiac-related mortality in controls, vs 0% in treated (p=0.059)

prevalence 6.2 million in US, > 670,000 new patients annually



### Cardiovascular franchise – chronic refractory ischemia



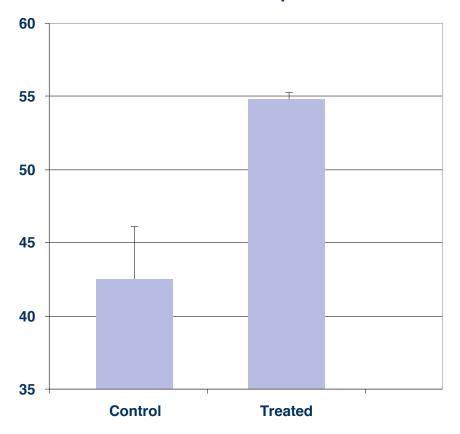
#### Perfusion results in humans

- VSDS score >0 indicates a perfusion defect, higher scores mean greater defect
- when the heart is stressed it does not receive sufficient blood flow
- treated patients with perfusion defect show statistically significant increased perfusion while control patients do not change over time
- increased new large blood vessel formation



#### Cardiovascular franchise – acute myocardial infarction

# Pre-clinical sheep model Left ventricular ejection fraction at 8 week follow up



#### Phase 2 trial design

- multi-country, 225 patient double blind randomized placebo controlled
- intracoronary infusion, two doses of MPCs vs saline (12.5M and 25M) randomized 1:1:1
- functional parameters MACE, reduction in infarct size
- additional functional efficacy assessments include LVEF, perfusion, volume changes, exercise treadmill test
- 24 month follow up

1.2 million new patients annually in US alone



#### Intravenous franchise – preclinical development

- high value product using systemic administration
- applications:
  - diabetes
  - inflammatory joint diseases (rheumatoid arthritis)
  - lung diseases (asthma)
  - neurological diseases (MS)
- we are generating compelling preclinical data in each of these areas to support early commencement of Phase 2 human trials
  - "best in breed" preclinical models, high predictive value



### Value inflexion points – near term

- commencement of Phase 3 cord blood expansion trial
- successful completion of Phase 2 heart failure trial
  - progression to Phase 3 pivotal trial
- commencement of intra-coronary heart attack Phase 2 trial
- successful completion of orthopedic Phase 2 trials
- commencement of disc repair Phase 2 trial
- moving diabetes and eye diseases into Phase 2 trials
- building the intravenous franchise
- further partnering opportunities optimal timing
- manufacturing strategic alliance



# mesoblast the regenerative medicine company

Leading the world in novel adult stem cell therapies

