



**Executive Director's Presentation
Annual General Meeting
27 November 2008**



Mesoblast Share Price Performance Relative to ASX All Ords

MESOBLAST FPO

as of 24-Nov-2008





Major Value Inflexion Points Since 2005

Technical

1. Demonstrated **scale-up** of manufacturing process
2. Demonstrated **safety** of manufacturing and cells in patients
3. Shown that **allogeneic** ("off-the-shelf") stem cells are **effective**

Clinical

4. **IND submissions** for four Phase 2a trials cleared by FDA < 30 days
5. **Patient enrolment** for Spinal Fusion, CHF, AMI, BMT Phase 2a trials

Commercial

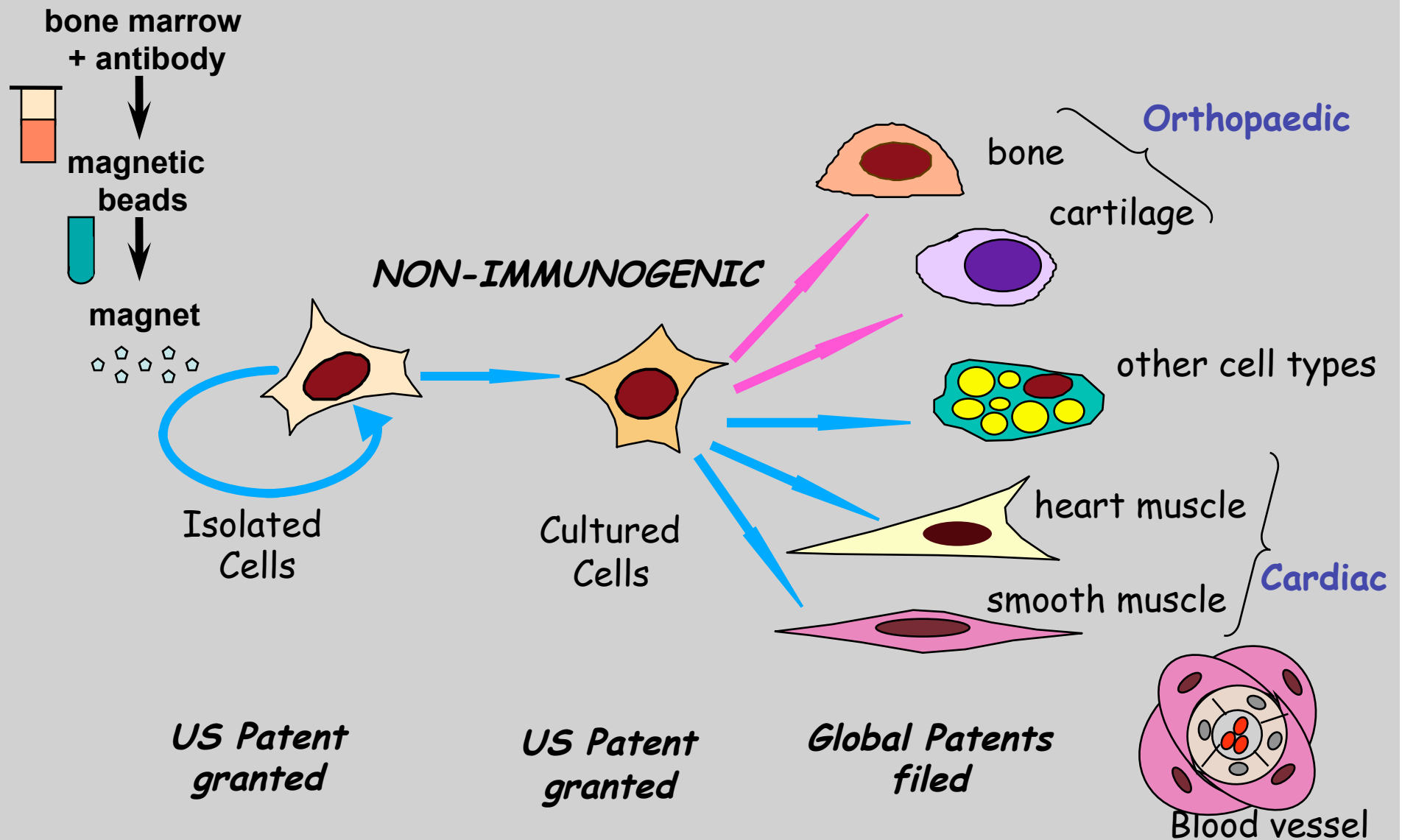
6. Issued two **US patents**: composition-of-matter & manufacturing
7. **Strategic alliance** with global Cardiovascular Pharma/Device Co.



Achieving Institutional Shareholder Support

- 1. transparent corporate structure and governance**
- 2. identifying value inflexion points as corporate drivers**
 - (a) commercial**
 - (b) technical**
 - (c) clinical**
- 3. risk mitigation strategies**
 - (a) seasoned management**
 - (b) multiple programs**
 - (c) early engagement of partners**
- 4. laying out achievable milestones**
- 5. keeping to rigorous timelines**
- 6. communicating effectively both strategy and results**

Robust Intellectual Property Underpins Commercial Products





Our products combine speed to market with a high margin business model

MPC products are biologic drugs in a bottle

- safer than small molecules
- greater predictability from pre-clinical to human trial end-points
- more rapid regulatory approval
- one donor -- thousands of patient doses
- unrelated (*allogeneic*) recipients
- centralized manufacturing (FDA and GMP compliant)
- frozen product immediately available -- good physician uptake
- low manufacturing costs, high margin
- ideal for large unmet markets



Road To FDA Approvals For An Allogeneic Stem Cell Product

Preclinical

- ✓ **characterize stem cell population**
- ✓ **proof-of-principle small animal studies**
- ✓ **optimize *ex vivo* culture process in GMP facility**
- ✓ **safety/dose-ranging studies in large animal models**

Clinical

- **phase 2 trials to identify safe, effective dose**
- **phase 3 trials to establish efficacy for product registration**



Lead Orthopaedic Programs

1. Spinal Fusion Indications

- ✓ lumbar: single-centre, FDA-cleared Phase 2a study
- cervical: upcoming Phase 2a trial
- anticipated Pivotal trial for intervertebral fusion 2009

2. Intervertebral disc repair/regeneration

- ✓ preclinical large animal study completed
- planned IND submission for Phase 2a clinical trial

3. Knee Osteoarthritis

- ✓ preclinical large animal models knee osteoarthritis completed
- Phase 2a clinical trial to commence shortly



Lead Orthopaedic Programs, c'td

4. Long bone repair

✓ Phase 1b trial long bone non-union completed

- 10 patients with 11 non-union fractures of tibial or femoral fractures
- range non-union 5-41 months
- three with failed autograft and BMP treatment
- all 10 patients followed for >12 months, no adverse events
- 9/11 fractures complete union, median 4.9 months



Programs In Partnership With US-Based Angioblast Systems, Inc.

1. Congestive Heart Failure (CHF)

FDA-cleared Phase 2a clinical trial in up to 60 patients
multicentre, 3 dose-escalation
20 patients each dose, randomised 3:1 treatment/control
first dose 17 patients enrolled, no safety concerns to date
evaluating cardiac functional recovery at 3, 6 and 12 months

2. Acute Myocardial Infarction (AMI)

FDA-cleared Phase 2a clinical trial in up to 25 patients
multicenter, dose escalation, no cell safety concerns to date
evaluating cardiac function at 6 and 12 months

3. Bone Marrow Transplantation, Expansion of Umbilical Cord Blood

Orphan Drug Designation

FDA-cleared Phase 1/2 clinical trial in up to 30 patients
evaluating safety, bone marrow engraftment, survival



***Programs In Partnership With US-Based
Angioblast Systems, Inc. (c'td)***

4. Age-Related Macular Degeneration (AMD) and Diabetic Retinopathy

**efficacy demonstrated in rodent study;
42-animal non-human GLP primate study completed
optimal dose identified for monotherapy
significant synergy in combination with anti-VEGF therapy
IND filing and Phase 2a trial planned for 2009**



Commercial Strategies For Our Biologicals

1. Taking Individual Applications to Market On Own

- highest capital and execution risk
- greatest shareholder return

2. Partnering Specific Applications

- share the risk, share the reward
- reduces risk of execution failure
e.g. Genetics Institute-Sofamor Danek/Medtronic
BMP-2 for bone growth (spine/trauma/other)

3. Broad-Based Partnering Of Platform Technology

- simultaneous development of multiple applications
- extensive resources applied to programs
e.g. Osiris-Genzyme
allogeneic adult stem cells