mesoblast the regenerative medicine company

Leading the world in novel adult stem cell therapies

J.P. Morgan 30th Annual Healthcare Conference San Francisco January 2012

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 relationships with Teva, Cephalon and Lonza and future benefits of those relationships; 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 forward-looking statements.



A risk managed business model

- proprietary platform technology delivers multi-product pipeline
 - multiple shots on goal
 - not dependent on success of any one product
- corporate partnerships manage execution risk
 - Teva provides global distribution capability, regulatory and clinical trial experience
 - Teva Phase 3 funding alleviates internal cash burn
 - Lonza provides best-in-breed process development & manufacturing capability, alleviates need for internal spend on manufacturing facility
- strong cash position (\$260m) enables simultaneous development of multiple products
 - Mesoblast has sufficient cash to advance new programs in parallel
 - investment in people with expertise in clinical development
- staged development program controls technical risk
 - managed transition from simple to complex indications and delivery modes
 - build on strong preclinical foundations and accumulated clinical experience



Technology



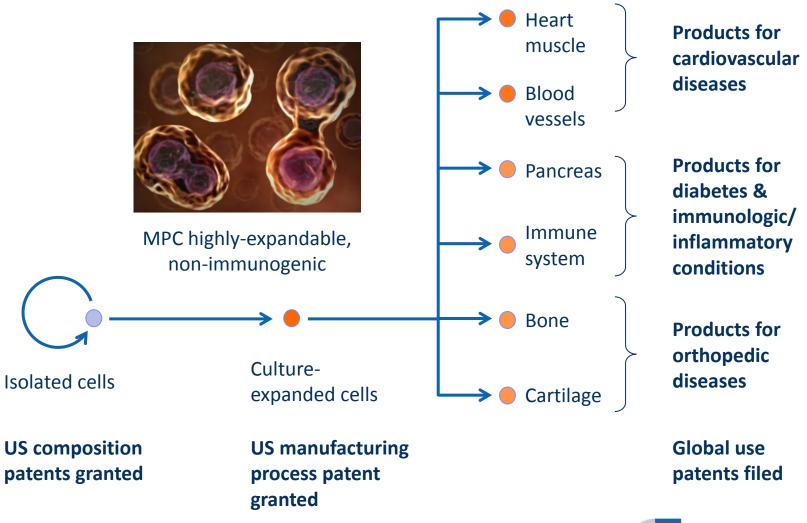


Overview of current stem cell universe

- stem cells are unspecialized cells that can renew themselves
 - can mature into specialized cell types such as muscle, nerve, bone, blood cells, etc
 - stem cells constantly renew and repair tissues in the body
- our mesenchymal precursor cells (MPC) are multipotent, easy to expand in large numbers, and can be used allogeneically ("off-the-shelf") due to reduced immune activation
- limitations of other stem cell types
 - embryonic stem cells and iPS
 - pluripotent can form most cells in the body
 - ethical and safety issues tumor potential
 - hematopoietic stem cells
 - can form limited cell types (blood cells, immune system)
 - difficult to expand
 - used autologously (patient's own cells) due to immune reactions



We own the IP on Mesenchymal Precursor Cells (MPCs)





Our proprietary adult stem cells

- potent, purified adult mesenchymal precursor cells
 - strong safety profile
 - avoid ethical and safety issues associated with embryonic stem cells
 - backed by strong patent position
- "off the shelf" classic pharmaceutical drug model
 - 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



Product Pipeline





Platform technology delivers multi-product pipeline

Cardiovascular and neurologic products

- Teva alliance delivers proven execution capability in major global markets
- cash from corporate partnership to fund rest of Mesoblast pipeline

Products for Type 2 diabetes and metabolic disease

- early diabetics
- kidney/heart/liver complications

Inflammatory/immunomodulatory products

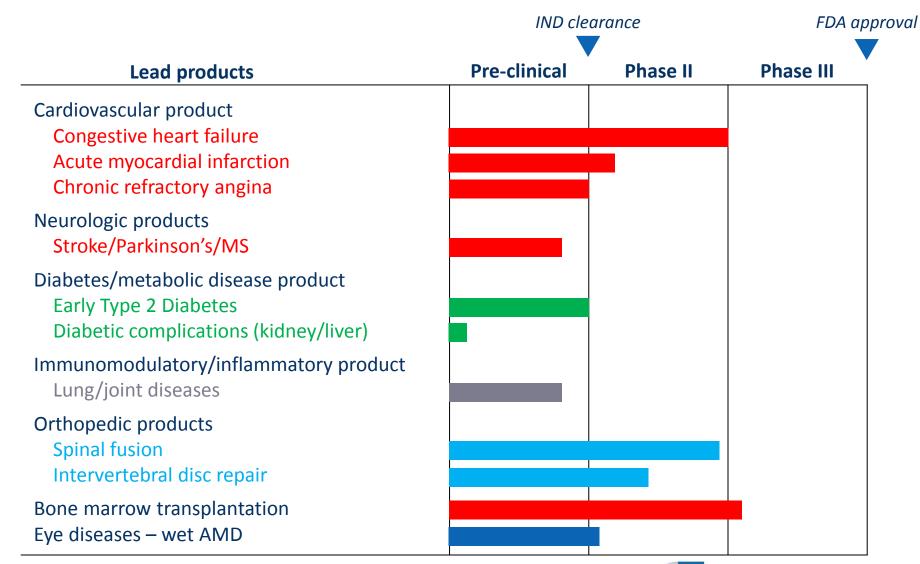
- lung diseases
- inflammatory joint diseases

Orthopedic products

- intervertebral disc repair
- stress fractures
- spinal fusion

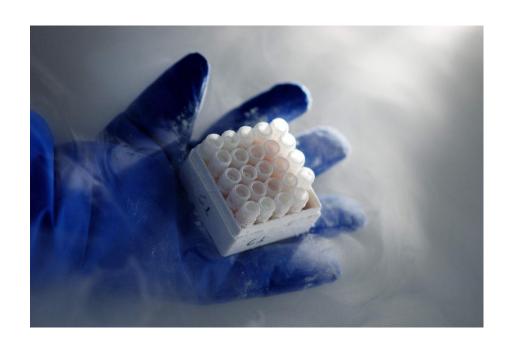


"Off-the-shelf" product franchises driving value creation





Strategic Partnerships





Teva strategic alliance

- Teva has exclusive worldwide commercialization rights to selected cardiovascular and neurologic indications, holds 19.99% stake in Mesoblast
- Teva responsible for funding Phase 2b and Phase 3 clinical development
- Mesoblast eligible to receive up to US\$1.7 billion in milestone payments, plus revenue split
- Mesoblast retains all manufacturing rights
- Mesoblast cash balance of US\$260 million to fund other major indications including
 - type 2 diabetes
 - inflammatory diseases of various tissues (eg lungs)
 - immunologic conditions (eg rheumatoid arthritis)
 - ophthalmic indications
 - orthopedic cartilage and bone conditions



Lonza manufacturing alliance is central to profitability

State-of-the-art manufacturing plant via strategic alliance with Lonza

- Lonza will supply clinical and long-term commercial MPC product needs globally
- Lonza to construct a purpose-built manufacturing facility exclusively for Mesoblast
- Mesoblast can buy out this facility at a pre-agreed purchase price
- Mesoblast will have exclusive access to Lonza's cell therapy facilities in Singapore

Mesoblast retains control of manufacture for all products

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

Commercial benefits

- reduced COGS, increased margins on sales price
- state-of-the-art, industrialized manufacturing process
 - R&D support for enhanced second generation products
 - leverage new technologies



Program Update





Cardiovascular franchise – congestive heart failure (CHF)

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

- 60 patient multi-center, randomized, controlled Phase 2 trial
- Class II-IV CHF, ejection fraction < 40% (high 6- and 12-month mortality)
- randomized 3:1 controls to MPCs at 25M, 75M or 150M cell doses
- cells injected by J&J NOGA Myostar™ catheter single injection
- primary stated endpoint of trial was safety and feasibility
- primary endpoint of safety successfully met, no adverse events associated with MPCs at any dose
- no clinically relevant immune responses to donor cells



Congestive heart failure – positive results presented at American Heart Association 2011 Annual Meeting

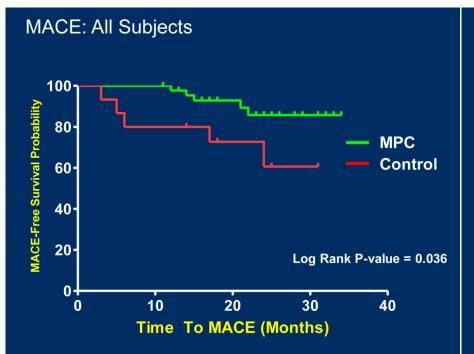
"In general, Phase 3 studies should use endpoints such as mortality and cardiovascular or heart failure hospitalizations, whereas endpoints, such as ejection fraction, that have not been validated as surrogates for clinical outcome are not considered to be acceptable as primary efficacy endpoints for pivotal trials."

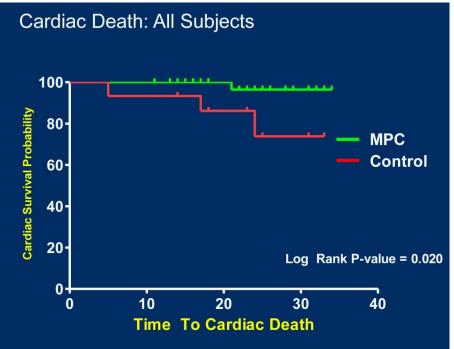
US FDA, Guidance for Industry, Cellular Therapy for Cardiac Disease October 2010

- MACE significantly reduced in MPC-treated patients over mean 22 month follow-up (p=0.036)
- MACE risk over time reduced by 78 % in MPC-treated patients vs controls (p=0.011), with 60-90% risk reduction at every MPC dose
- cardiac mortality significantly reduced in MPC-treated patients compared with controls over mean 22 month follow-up (2% vs 20%, p=0.02)
- highest dose of Revascor™ completely prevented any deaths or episodes of heart failure hospitalization over 18 months of follow-up
- highest dose showed evidence of remodeling (reduction in heart volumes) and improvement in functional capacity (increased walking distance), which are key parameters in congestive heart failure
- Revascor™ anticipated to progress to Phase 3 trial in first half of 2012



Congestive heart failure – Kaplan Meier plots







Intravenous product franchise – Type 2 diabetes pre-clinical study

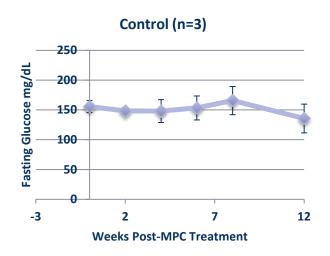
- 17 non-human primates with natural Type 2 diabetes associated with obesity
- dose-ranging study evaluating effect of single intravenous injection of Mesoblast's allogeneic MPCs over twelve weeks
- controls (n=3) received a single saline injection, four groups of treated subjects (3-4 per group) received one of 4 escalating doses of MPCs (0.1, 0.3, 1 and 2 million MPCs/kg).
- fasting blood glucose and C-reactive protein measured at 0, 2, 4, 6, 8, 12
 weeks

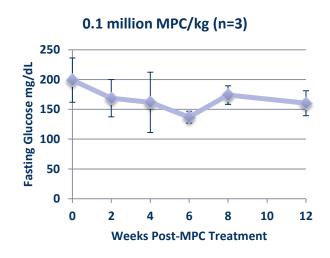
CRP > 3mg/L is a major established risk factor for heart attack and death in Type 2 diabetics

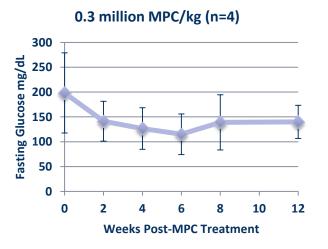
Study objectives were to see if a single MPC injection could have durable glucose-lowering effect, and assess potential MPC cardioprotective effects as measured by CRP levels over time

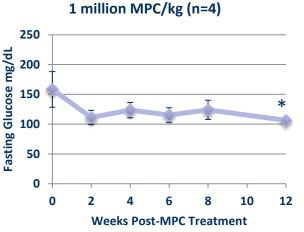


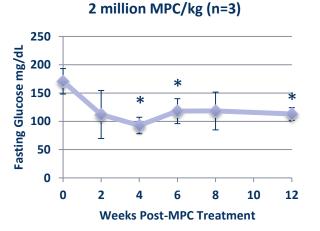
Sustained and significant reduction in fasting blood glucose levels 12 weeks after single MPC injection of 1 or 2 million MPC/kg







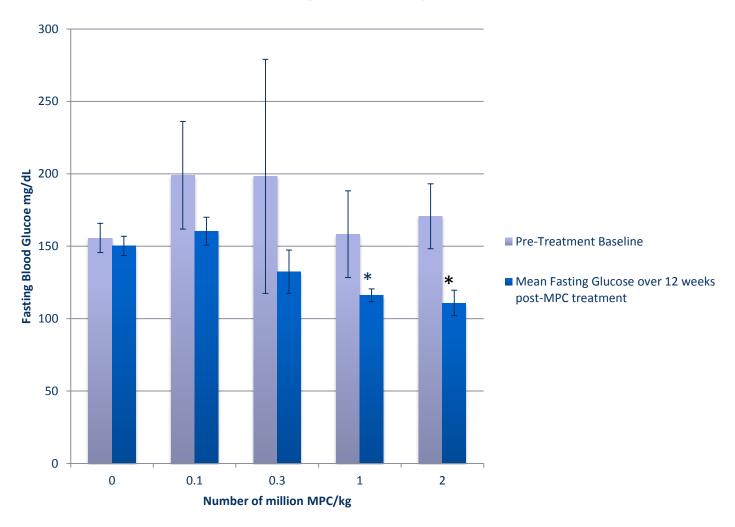






^{*} Significant at P<0.05 compared to week 0 baseline

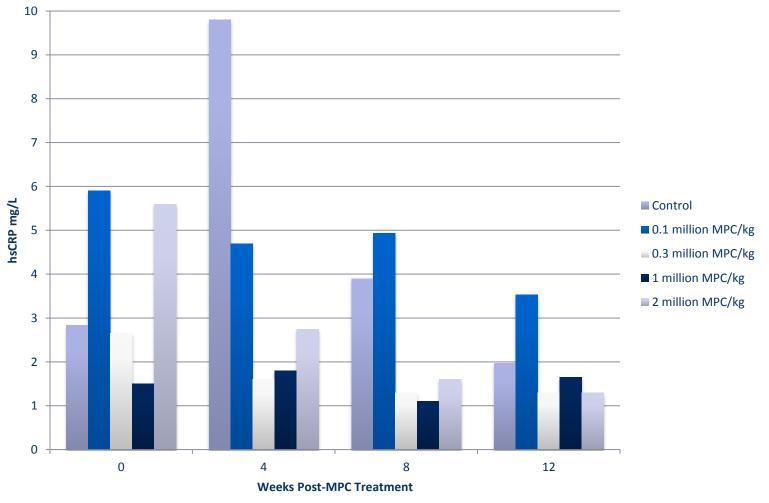
Significant reduction in mean fasting blood glucose levels over 12 week study period relative to baseline after single MPC injection of 1 or 2 million MPC/kg







Single injections of 0.3, 1 or 2 million MPC/kg maintain mean CRP levels below 3 mg/l for entire 12 week study period; controls maintain CRP levels > 3mg/l for 8/12 weeks





Summary and Conclusions from Type 2 Diabetes Pre-Clinical Study

- Single injection of 1 or 2 million MPC/kg caused significant and sustained reductions in fasting blood glucose levels over 12 weeks; no reductions in blood glucose levels were seen in controls
- C-reactive protein (CRP) levels were < 3 mg/L throughout the entire 12 week study period after single MPC injection of 0.3, 1 or 2 million MPC/kg; controls had CRP levels > 3 mg/L for 8/12 weeks
- Data demonstrate sustained 12 week durability of glucose lowering effect by single intravenous injection of allogeneic MPC; accompanying sustained reduction in CRP levels suggest a potential cardioprotective effect of the MPC
- Plan to commence first human Phase 2 clinical in patients with Type 2 Diabetes to confirm the glucose lowering effects of a single intravenous injection of MPC over a 12 week study period
- Plan to progress to Phase 2 clinical trials in patients with Type 2 Diabetes and high risk of death from cardiovascular causes



Corporate Overview





Investment snapshot

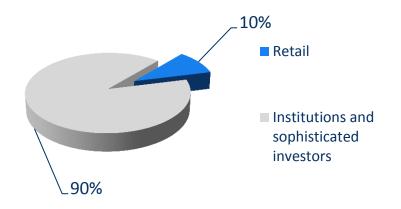
Mesoblast is a public company, listed on the Australian Securities Exchange since 2004.

It is included in the S&P/ASX 200 Index.

Issued shares	280m
Current share price	US\$6.67
Cash available (approx)	US\$260m
Market capitalization	US\$1,870m

Results (A\$m except per share data)	2011	2010
Total revenue & other income	120.9	0.8
Operating expenses		
R&D	15.3	7.6
Management	11.8	3.6
Other	1.5	4.4
Profit / losses (before tax)	92.2	(14.8)
EPS basic – cents per share	41.8	(10.5)
EPS diluted – cents per share	39.8	(10.5)

Mesoblast ownership





2011 - major accomplishments

- strategic alliance with Teva/Cephalon for selected product commercialization
- strategic alliance with Lonza for long-term manufacturing capacity
- expanded cardiovascular franchise to cover heart failure, heart attack and chronic angina
- completed congestive heart failure Phase 2 trial, special presentation at American Heart Association meeting
- expanded spine franchise: commenced degenerative disc repair Phase 2 trial,
 complements ongoing Phase 2 spinal fusion trials
- successful pre-clinical Type 2 diabetes study, ready to begin first Phase 2 trial for intravenous product
- commenced Phase 2 trial in wet age-related macular degeneration



Value inflexion points – near term

- Teva + Mesoblast meeting with FDA re commencement Phase 3 trial for congestive heart failure
- completion of Phase 2 spinal fusion trials
- completion of Phase 2 disc repair trial
- FDA clearance of IND to begin Phase 2 trial in Type 2 Diabetes
- expanding the intravenous product franchise, e.g. lung diseases
- further partnering opportunities optimal timing



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