

asx announcement

A YEAR OF TRANSFORMATION

Address by Mesoblast Chairman Brian Jamieson 2011 Annual General Meeting

On behalf of the Board of Directors, I am very pleased to welcome you to the 2011 Annual General Meeting of Mesoblast Limited.

I am proud to report the progress we've made over the past year at Mesoblast. As a leading company in the life sciences, we have had a number of transformative events during the course of the past 12 months, and I want to share these with you in my brief remarks.

Recent developments, in terms of both our business relationships and our clinical trial programs, have allowed us to further solidify our position of dominance in regenerative medicine. With stem cell therapy at its core, regenerative medicine is an area we see as having vast potential for human health and the evolution of treatments for major diseases.

As you know, last December we made a seminal announcement – Mesoblast entered an alliance with United States-based Cephalon Inc to develop and commercialize our proprietary adult stem cell therapeutics. The alliance is focused on degenerative conditions of the cardiovascular and central nervous systems.

The agreement, which included a substantial upfront payment of US\$130 million, as well as up to US\$1.7 billion in milestone payments from Cephalon, has helped Mesoblast to accelerate its clinical programs over the past year, giving us the flexibility to pursue multiple, concurrent clinical trials on our own. This is unlike many other international life science companies who have been adversely impacted by the current economic crisis and have had to pare back or shutter key programs.

In October of this year, Cephalon was acquired by Israel-based Teva Pharmaceutical Industries Ltd. From the beginning, Teva has signalled the importance they attach to our adult stem cell platform and programs. During a recent corporate presentation, Teva highlighted Mesoblast's technology as one of the most important areas of innovation within their global collaborative network. Teva has been very supportive, our teams work with them closely in planning next steps in clinical development, and I believe both companies have much to offer each other.

Another major event in 2011 was our signing of a strategic global manufacturing alliance with Switzerland-based Lonza Group, a world leading biologics suppliers to the pharmaceutical, healthcare and life science industries. The alliance with Lonza will provide us with significant commercial advantages, including certainty of capacity to meet long-term global supply of our adult stem cell products.



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I mentioned the progress of our development programs, and indeed we've seen very encouraging clinical and preclinical results for our adult stem cell products across major indications where this a critical need for novel and more efficacious therapies – heart failure, heart attacks, chronic angina, Type 2 diabetes, degenerative disc disease, and age-related macular degeneration.

Most recently, we announced independently reviewed mid-stage clinical results for Revascor $^{\text{TM}}$, our proprietary product for cardiovascular diseases. This is a patient population that otherwise has few treatment options, and the only method of treating end-stage heart failure currently is a heart transplant or a mechanical assist device.

Revascor[™] was safe and well-tolerated at all doses, with no clinically relevant immune responses to donor cells. Treatment with Revascor[™] significantly reduced cardiac mortality and major adverse cardiac events in patients with congestive heart failure. The highest dose of Revascor[™] completely prevented any episodes of heart failure hospitalization over 18 months of follow-up, which is a major hard endpoint that the FDA wants to see emulated in a subsequent Phase 3 trial. Based on these outstanding results, Revascor[™] is expected to enter Phase 3, the last stage of clinical testing, in multiple centers worldwide in the first half of 2012.

Mesoblast also received clearance from the United States Food and Drug Administration to enter Phase 3 testing for bone marrow regeneration in patients who have been treated for blood cancers. Results of a study sponsored by the acclaimed MD Anderson Cancer Center showed our MPCs accelerated recovery of blood cells and were associated with excellent 100-day patient survival and low rates of graft immune responses.

We also initiated a Phase 2 clinical trial of our MPC product for the treatment of low back pain and degenerative disc disease this past August. This is another major global disease that we are targeting with a highly innovative and effective clinical approach.

We are aiming to replicate preclinical study results where a single, minimally-invasive injection of our MPCs into severely damaged intervertebral discs resulted in significant reversal of the degenerative process and regrowth of disc cartilage.

This past year, we also received clearance from the European Medicines Agency to begin a Phase 2 clinical trial in Europe using Revascor in conjunction with angioplasty and stent procedures to prevent heart failure after a major heart attack. The preclinical data was very compelling, and formed the basis for this innovative clinical trial.

Additionally, we gained clearance from the Singapore Health Sciences Authority to use our cells to treat a form of age-related macular degeneration, which is the leading cause of blindness in the elderly in industrialized nations. Once again, we hope to replicate very promising preclinical trial results.

Our corporate strategy is to increasingly target the emerging and very accessible large Asian healthcare markets, and this is in line with the Lonza manufacturing agreement which provides Mesoblast with exclusive access to Lonza's cell therapy facilities in Singapore for the manufacture of our off-the-shelf products.



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And this month, we reported very promising preclinical results of our MPC product for Type 2 diabetes, which showed that a single injection of our off-the-shelf cells significantly lowered blood sugar levels for up to eight weeks in non-human primates with Type 2 diabetes. A direct correlation between reductions in fasting blood glucose levels over time and reductions in a major predictor of cardiovascular risk in Type 2 diabetic patients was also demonstrated. After a positive meeting with the FDA just last week, we hope to take this to the clinic in a Phase 2 study in the first quarter of 2012.

As you can see, we have had an outstanding year. We expect even greater accomplishments in the near future and anticipate a healthy flow of news and key milestones into 2012 and beyond.

While Mesoblast's corporate headquarters are in Australia, we have also established a strong presence in the key healthcare market of the United States, with our office in New York City focusing on our clinical, regulatory and manufacturing activities.

Essentially Mesoblast is a global organization. Our partners are international, and the Company's adult stem cell products are the subject of active programs at many of the leading research institutions and organizations in the United States and Europe, Asia and Australia. We have diversified our shareholder base, increasing the number of global institutional holdings as well as retail participation in major markets.

We are well-financed and well-supported, with approximately \$256 million cash on hand. This gives us true flexibility to establish the broadest scope of application for our promising, adult-derived Mesenchymal Precursor Cells.

We attract the best and the brightest because we want to change and believe we can change medical care and quality of life for patients worldwide.

In looking back over the previous year, I'd like to acknowledge the strong teams that form the core of our company. We have brought in key hires with pivotal experience in the industry. We are proud to have built a diverse group with complementary skills and have maintained gender diversity by attracting a number of women to senior roles within the Company.

I would also like to acknowledge the expertise and broad range of skills and experience that my fellow Board members bring to the table and their steadfast commitment to exemplary corporate governance.

As you can see, we have had an outstanding year and we have travelled a great distance towards achieving what we hope is the first in a series of approvals for breakthrough products that will address major diseases with well-defined, unmet clinical needs.

Thank you for giving me the opportunity to present the Mesoblast story to you. I would now like to welcome Mesoblast's exceptional Chief Executive, Professor Silviu Itescu, to elaborate further on the path to commercialization and our outstanding results to date.

Melbourne, Australia

24 November 2011

mesoblast the regenerative medicine company



Leading the world in novel adult stem cell therapies

Annual General Meeting 24 November 2011

Silviu Itescu
Chief Executive

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

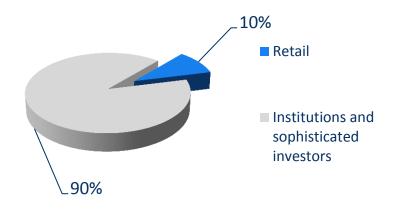
Mesoblast is a public company, listed on the Australian Securities Exchange since 2004.

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

Issued shares	280m
Current share price	A\$6.64
Cash available (approx)	A\$256m
Market capitalization	A\$1,860m
ivial ket capitalization	A\$1,000

Results (\$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 Cephalon Inc. 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
- commenced Phase 3 trial in bone marrow transplantation



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" 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



Building a successful biologics life sciences company: understanding and managing corporate risk

- Platform technology delivers multi-product pipeline
 - Multiple shots on goal
 - Not dependent on success of any one product
- Corporate partnerships manage execution risk
 - Teva/Cephalon provides global distribution capability
 - Teva/Cephalon funding of Phase 3 trials alleviates internal cash burn
 - Teva/Cephalon team brings regulatory and clinical trial experience
 - Lonza provides best-in-breed process development & manufacturing capability,
 alleviates internal need to spend on manufacturing facility
- Strong cash position 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 foundations (R&D/pre-clinical data)



The Mesoblast value proposition – the three pillars

The Teva 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

Orthopedic pipeline

- intervertebral disc repair
- spinal fusion
- stress fractures

Intravenous product pipeline

- Type 2 diabetes
- inflammatory diseases of various tissues (eg lungs)
- immunologic conditions (eg rheumatoid arthritis)



Teva (Cephalon) strategic alliance

- Teva/Cephalon received exclusive worldwide commercialization rights to selected cardiovascular and neurologic indications
- Teva/Cephalon responsible for funding Phase 2b and Phase 3 clinical development
- Mesoblast received upfront fee of US\$130 million, plus eligible for up to US\$1.7
 billion in milestone payments, plus revenue split, retains all manufacturing rights
- Teva/Cephalon acquired 19.99% stake in Mesoblast for \$243m outlay
- Mesoblast cash balance of \$256 million to fund other major indications including
 - Diabetes
 - inflammatory diseases of various tissues (eg lungs)
 - immunologic conditions (eg rheumatoid arthritis)
 - ophthalmic indications
 - orthopedic cartilage and bone conditions
- Teva acquisition of Cephalon a major further validation of Mesoblast's technology and product pipeline

Global 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

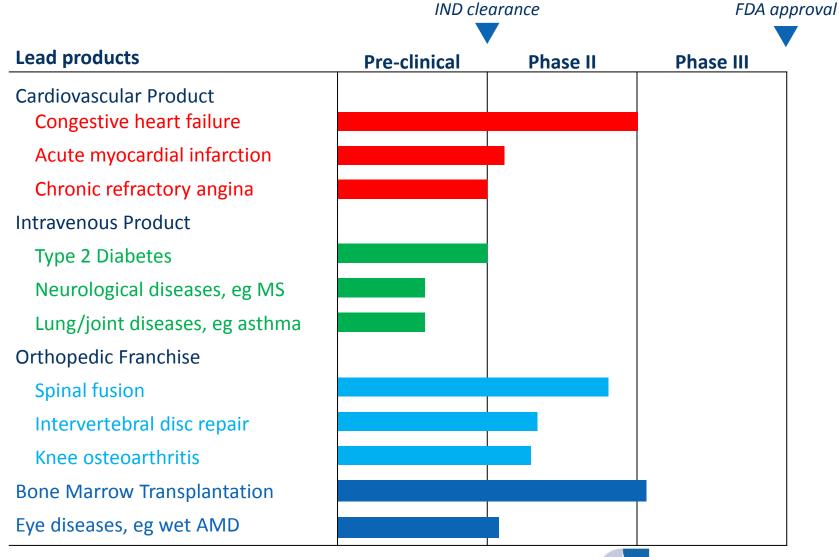
- product delineation for distribution partners
- maintain optimal product pricing differences

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



"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)
- 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 successfully met, no adverse events associated with MPCs at any dose
- no clinically relevant immune responses to donor cells

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



Congestive Heart Failure – American Heart Association Annual Meeting 2011: Phase 2 trial successfully met the only endpoints FDA accepts for Phase 3 approval

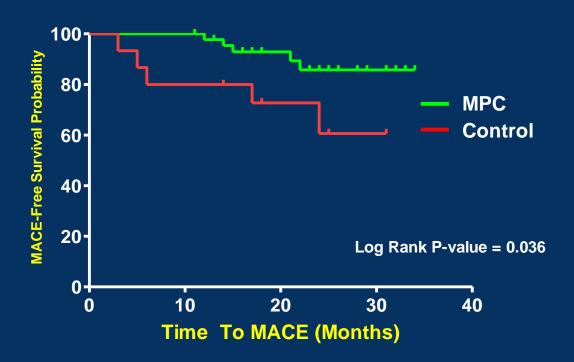
"In general, Phase 3 studies should use endpoints such as mortality and cardiovascular or heart failure hospitalizations, whereas endpoints, such as ejection fraction, that have not been validated as surrogates for clinical outcome are not considered to be acceptable as primary efficacy endpoints for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

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

mesoblast

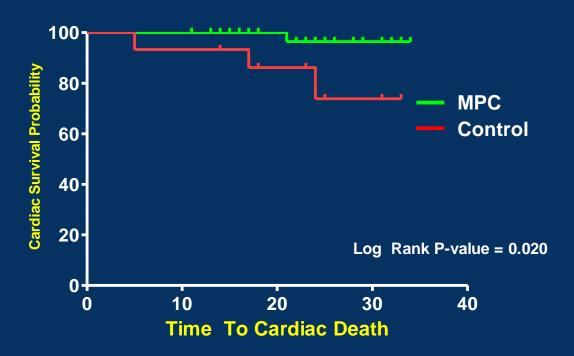
- Major Adverse Cardiac Events (MACE, defined as cardiac death, heart attack or revascularization procedure) significantly reduced in MPC-treated patients over mean 22 months follow-up (p=0.036)
- MACE risk over time reduced by 78% in MPC-treated patients vs controls (p=0.011), with 60-90% risk reduction seen at every MPC dose
- Cardiac mortality significantly reduced in MPC-treated patients compared with controls over a mean follow-up of 22 months (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
- High dose group showed evidence of remodeling (reduction in heart volumes) and improvement in functional capacity (increased walking distance), which are key parameters in congestive heart failure
- 12 Revascor[™] anticipated to progress to Phase 3 trial in first half of 2012

MACE: All Subjects





Cardiac Death: All Subjects





Intravenous franchise – preclinical development

- high value product using systemic administration
- applications:
 - Type 2 diabetes
 - Lung diseases (inflammatory conditions, asthma)
 - Osteoporosis
 - Inflammatory joint diseases (rheumatoid arthritis)
 - 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



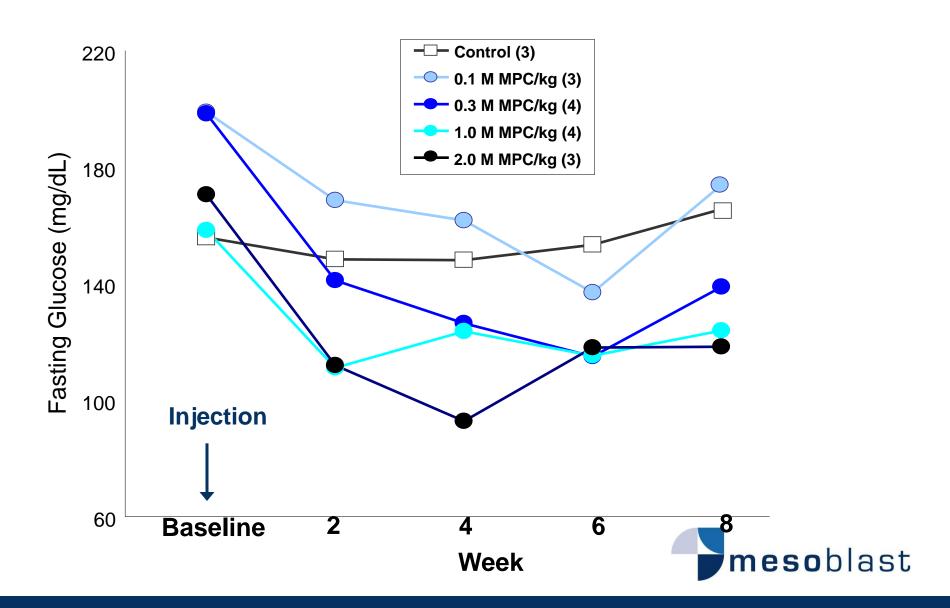
Intravenous franchise – Type 2 Diabetes Pre-Clinical Study

- 17 non-human primates with obesity and Type 2 diabetes
- dose-ranging study evaluating effect of single intravenous injection of Mesoblast's allogeneic MPCs over eight 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 (CRP) measured at 0, 2, 4, 6, 8
 weeks

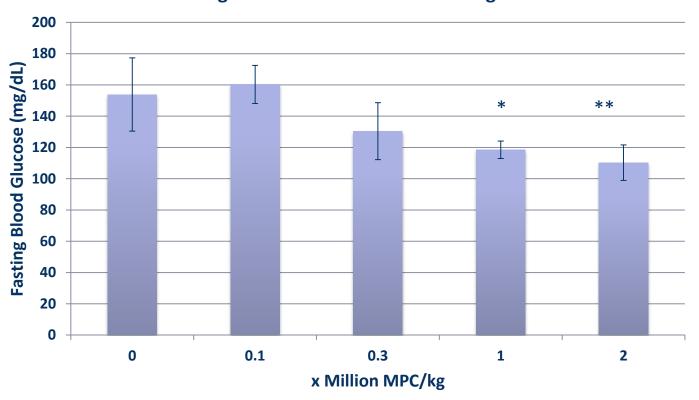
CRP > 3mg/dL is a major established risk factor for heart attacks and death in Type 2 Diabetics



Effect of MPC or Saline Injection on Fasting Glucose in Nonhuman Primates With Type 2 Diabetes



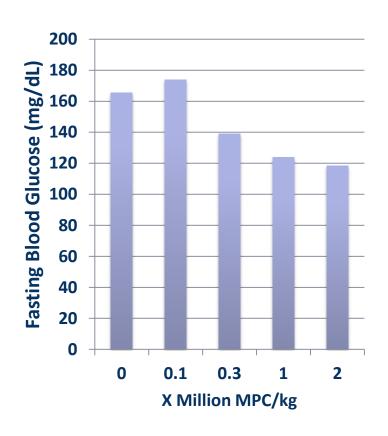
Dose-Dependent Effect Of Single Intravenous MPC Injection On Mean Fasting Blood Glucose Levels Over Eight Weeks

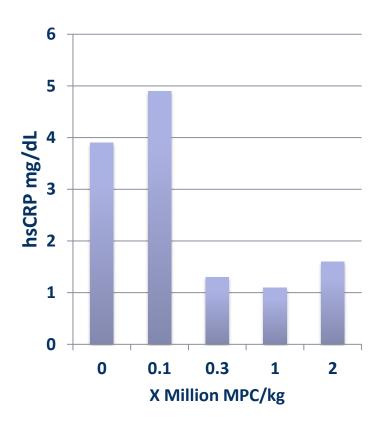


** P<0.05 compared to controls



Dose-Dependent Effects On Blood Glucose And CRP Levels Eight Weeks After A Single Injection Of Allogeneic MPCs: Are MPCs Cardioprotective In Type 2 Diabetes?







Value inflexion points – near term

- completion of Phase 2 heart failure trial progression to Phase 3 pivotal trial
- completion of orthopedic Phase 2 spinal fusion trials
- completion of disc repair Phase 2 trial
- moving diabetes into Phase 2 trials
- building the intravenous franchise
- further partnering opportunities optimal timing



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