mesoblast

the regenerative medicine company

Leading the world in novel adult stem cell therapies

2013 Half-Year Financial Results

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

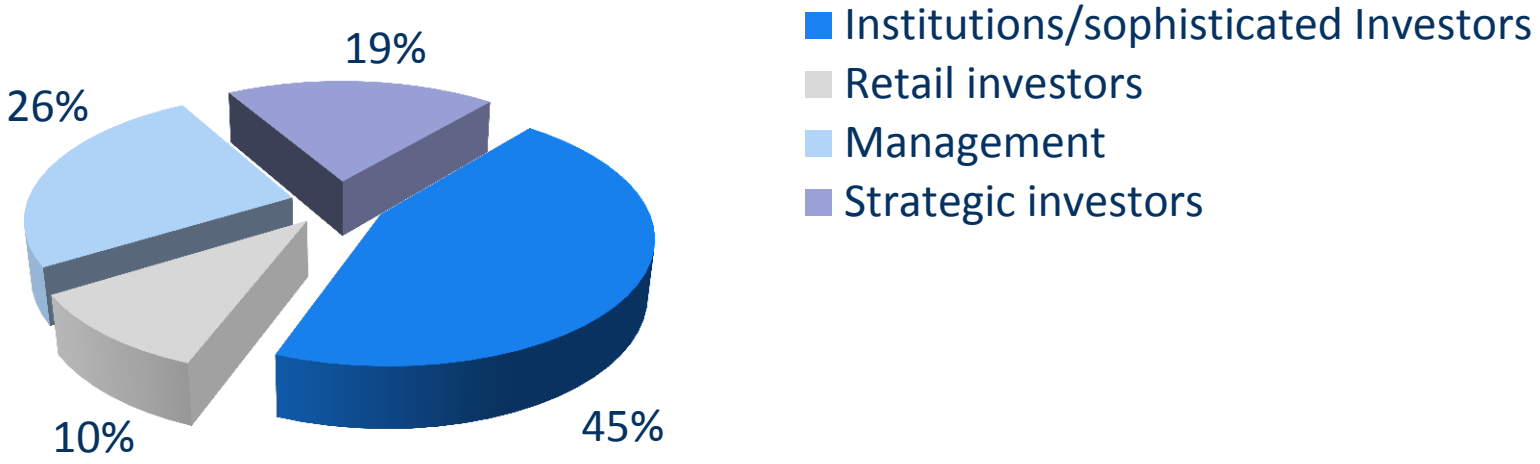
This presentation, including any comments made during or following the presentation, may contain forward-looking statements that are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These statements may relate to, but are not limited to: expectations regarding 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.

mesoblast

Shareholder value and ownership

Market valuation	
Issued shares	287.8 million
Current share price (market close, 8 February 2013)	$7.07
Market capitalization	$2,035 million

Shareholder ownership



mesoblast

Cash

CASH RESERVES		31 December 2012 $m	30 June 2012 $m	Half-Year Movement $m
Cash reserves		**178.6**	**206.7**	**(28.1)**

CASH FLOWS	Half-year 2012 $m	Half-year 2011 $m	Half-Year Movement $m
Cash outflow from operations (before tax)	**33.8**	**29.8**	**4.0**
Tax (refund)/payment	**(3.3)**	**7.1**	**(10.4)**
Cash outflow from operating activities	**30.5**	**36.9**	**(6.4)**

- Strong cash position to pursue our key areas of MPC product development in parallel in order to most efficiently bring our products to market, either on our own or with strategic distribution partners
- Movement in cash-flow from operations (before tax) for the half-year of $33.8m approximates an annual cash-burn of $67.6m, reflecting an increase in clinical activities

mesoblast

Results – P&L

(PROFIT)/LOSS before tax	Half-year 2012 $m	Half-year 2011 $m	Movement $m
Revenue & other income	**14.7**	**19.0**	**(4.3)**
Expenses from operations	**35.9**	**32.0**	**3.9**
Made up of:			
Research and development	*17.2*	*12.7*	*4.5*
Manufacturing commercialization	*8.9*	*7.9*	*1.0*
Management and administration	*9.8*	*11.4*	*(1.6)*
Share-based payments expense	**6.6**	**4.6**	**2.0**
Net loss before tax	**27.8**	**17.6**	**10.2**

- The apparent decrease in revenue is principally due to an extension of the period over which the USD130 million upfront payment received in December 2010 is being amortized.
- The increase in expenditures is in line with expectations given our broadening strategy for clinical development as we gain greater understanding of the broad mechanisms of action (MOA) of our unique MPCs. Specifically we have:
  - initiated new Phase 2 clinical programs in diabetes and rheumatoid arthritis;
  - completed recruitment in the 100 patient Phase 2 trial for disc repair;
  - initiated new preclinical studies in inflammatory lung diseases;
  - increased product manufacturing to support these programs;
  - reduced corporate overheads through greater controls and efficiencies.

mesoblast

Corporate Partnerships Reduce Execution Risk

Teva alliance

- partnership focus on cardiovascular, neurologic diseases
- lead product for congestive heart failure – leading cause of hospitalization in industrialized world
- provides Phase 3 clinical and regulatory expertise
- provides funding for partnered programs
- provides global distribution strength
- allows Mesoblast to focus its resources on broadening product offerings and on optimizing manufacturing.

mesoblast

Corporate Partnerships Reduce Execution Risk

Manufacturing

- corporate strategy to manufacture across multiple sites in US and other jurisdictions to offset risks of single site dependence
- Lonza partnership provides global manufacturing capabilities
- exclusive access to state-of-the-art Singapore facility for allogeneic cell manufacture reduces risk of supply constraint
- new Singapore site will support clinical trial and early commercial supply
- partnership alleviates need for Mesoblast internal spend on manufacturing facility, and will provide significantly larger facility for commercial supply on first product approval
- agreement with US FDA on manufacturing process to supply MPCs for Phase 3 clinical trials.

mesoblast

Robust Intellectual Property Patent Estate

- Mesoblast has exclusive worldwide rights to a series of patent families covering compositions, methods of manufacture, and uses of MPCs for product commercialization. Patents have been granted or are pending in various jurisdictions, including the United States, Europe, and Asia

- Granted patents valid through to 2029 in world's largest established healthcare market, the United States, confer Mesoblast with exclusive rights to methods of manufacturing and compositions-of-matter covering our current products

- Two additional new granted patents provide Mesoblast with exclusive MPC product commercial rights and protection through to 2025 in China. These patents provide composition-of-matter protection for MPC products derived from an unlimited range of tissue sources such as bone marrow, adipose tissue, placenta, umbilical cord, and dental pulp.

Granted United States and Chinese patents underpin Mesoblast's long-term corporate strategy to target the world's largest established and emerging markets for regenerative medicines, and to protect its manufacturing processes and know-how.

mesoblast

Mechanisms of Action (MOA) Drive Product Development

Mesoblast's strategic product focus is guided by specific MOAs of our MPCs.

The MPCs respond to signals from inflammation and/or tissue damage by releasing a range of factors which :

- induce polarization of pro-inflammatory monocytes to a non-inflammatory phenotype
- inhibit activated T cells and induce regulatory T cells
- stimulate blood vessel growth and maturation, and reverse endothelial dysfunction; and
- increase survival and improve function of cardiac muscle cells, cells of central nervous system, bone-forming cells, and cartilage-producing cells.

Control of Manufacturing Ensures Product Delineation

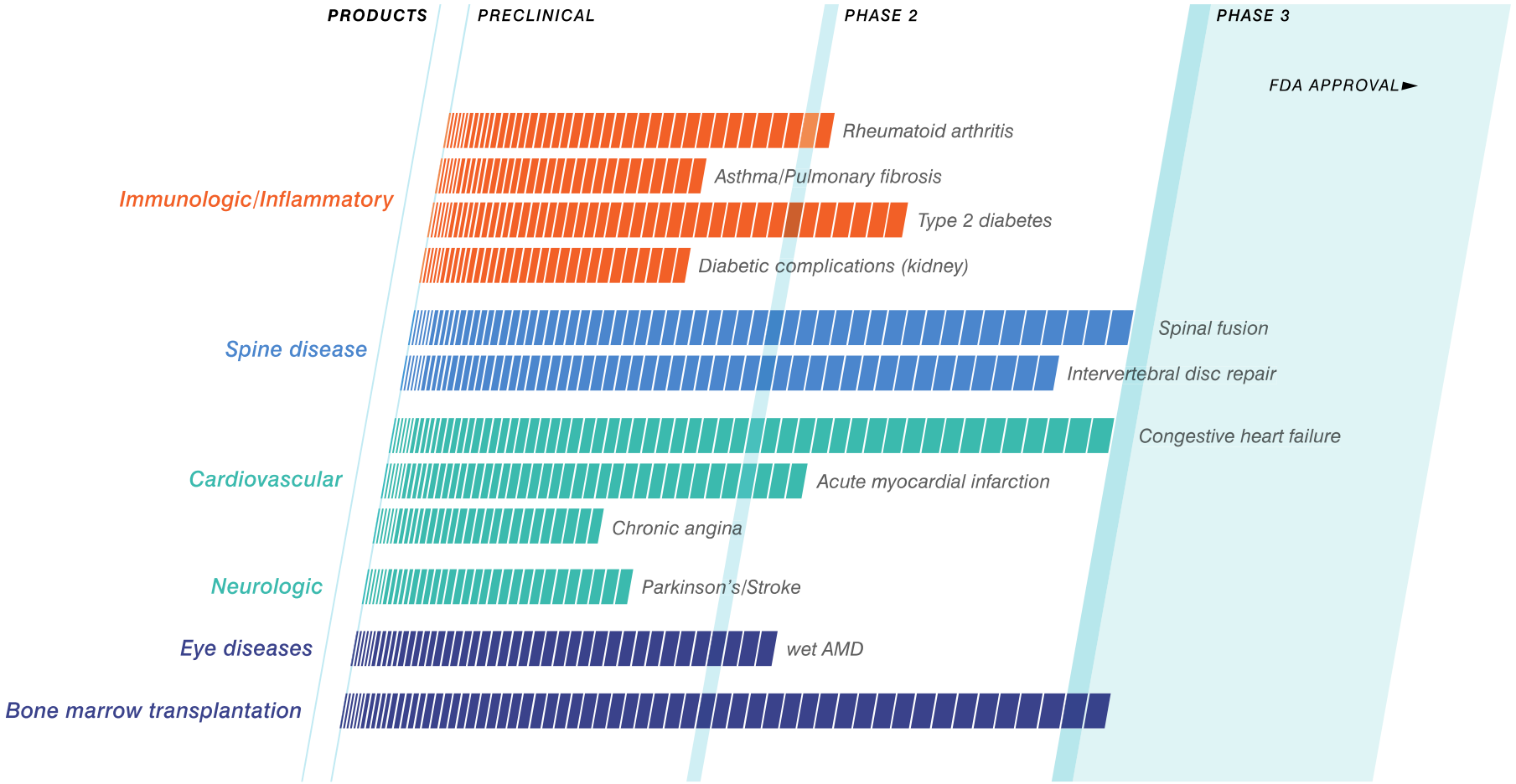
Mesoblast can delineate products to support and separate partner markets, optimize reimbursement strategies, and manage product lifecycles.

Innovative R&D delivers product delineation through:

- changes in formulation or dosage
- products derived from different tissue sources (e.g. bone marrow, adipose, dental pulp)
- combination therapies using different modes of delivery or devices
- biologic modifications of cells

mesoblast

MPC Platform Delivers Multi-Product Pipeline



Key Areas Targeted for Mesoblast's MPC Product Development

Mesoblast's strategic product development focus is in three major and distinct areas:

I. Systemic diseases of excessive inflammation and immunity which can be addressed by intravenous administration of MPCs

II. Orthopedic diseases of the spine where our MPCs can be locally administered to generate new bone and repair intervertebral discs

III. Cardiovascular diseases where our MPC products can be locally administered to improve heart function.

I. Products Delivered Intravenously for Diseases of Inflammation and Immunity

- Mesoblast's MPCs have been shown in preclinical studies to have a broad immunomodulatory mechanism of action (MOA)
- MPCs simultaneously inhibit multiple pathways of inflammation and immune activation, including T cells and monocytes
- Mesoblast’s intravenous MPC product is being developed as an immunomodulatory agent to treat prevalent systemic disorders caused by excessive inflammation and activation of multiple immune pathways
- Targeted disorders include inflammatory joint diseases such as rheumatoid arthritis, type 2 diabetes and its complications, particularly diabetic kidney disease, and inflammatory lung diseases, such as asthma and pulmonary fibrosis.

mesoblast

Rheumatoid Arthritis

- In January 2013 Mesoblast received FDA clearance to begin Phase 2 trial of allogeneic MPCs in 48 patients patients with active Rheumatoid Arthritis (RA)
- Trial will be randomized, double-blind placebo-controlled dose escalation study to evaluate the safety and effectiveness of a single intravenous infusion of two MPC dose levels over an initial period of 3 months in patients who have had poor or incomplete responses to biologic inhibitors of the TNF-alpha pathway
- In an animal model of RA, MPC treatment significantly decreased the T cell and monocyte derived inflammatory cytokines TNF-alpha, IL-6 and IL-17 in the diseased joint and reduced tissue pathology
- MOA provides the rationale for strategic development of MPCs in RA both in patients with incomplete responses to biologic inhibitors of the TNF-alpha pathway alone and as a first-line biologic in those not responding to conventional anti-rheumatic agents
- In addition, a second Phase 2 trial of MPCs as a first-line biologic treatment for active RA is planned to commence in Europe in 1H 2013.

mesoblast

Type 2 Diabetes and Diabetic Kidney Disease

- Type 2 diabetes is a disease of chronic inflammation which results in insulin resistance in fat tissues and vascular complications in various organs, including the kidneys, heart and eyes

- Mesoblast is in the midst of a Phase 2 clinical trial in 60 patients with early type 2 diabetes not adequately maintained on oral glucose-reducing agents. The patients are being evaluated over 12 weeks for effectiveness of a single intravenous MPC dose on changes in various inflammatory markers, including C-reactive protein (C-RP), and on blood glucose control

- We expect that this multi-center trial will set the foundation for evaluating MPCs in the treatment of patients with more advanced diabetes in order to target the life-threatening complications of the disease, such as renal failure and cardiovascular disease

- Mesoblast plans to initiate a Phase 2 trial in the second half of FY 2013 to evaluate whether a single intravenous MPC injection can stabilize or reverse end-stage kidney disease in diabetics.

mesoblast

II. Products Delivered Locally for Orthopedic Diseases of the Spine

Spine Fusion Surgery for Advanced Intervertebral Disc Degeneration

- In Mesoblast's 24-patient multi-center randomized US trial, two doses of MPCs, 25M or 75M, were compared against bone autograft for interbody lumbar spinal fusion surgery
- There were no MPC-related serious adverse events and no ectopic bone formation
- MPC treated groups had 30-43% lower mean estimated blood loss during surgery compared to the autograft treatment group ($p<0.05$ for the 25M group)
- At 12 months, all three treatment groups had similar rates of fusion success, with clinically significant and comparable improvement in low back pain and function across all groups
- The results showed that Mesoblast's MPC product NeoFuse® was safe and as effective for use in interbody lumbar fusion surgery as the gold standard, bone autograft, without the need for a second surgical procedure and its attendant morbidity risks
- These results support the progression of clinical development of NeoFuse® in a proposed Phase 3 trial in interbody lumbar fusion surgery.

mesoblast

Non-Surgical Restoration of Early Intervertebral Disc Disease

- Non-surgical restoration of early disc damage represents a much larger market opportunity than surgical fusion, with no existing alternative therapies available to reduce back pain and improve function
- Preclinical sheep study showed that non-surgical injection of Mesoblast's allogeneic MPCs restored proteoglycan content and reversed abnormal histopathology in model of degenerative disc disease
- Mesoblast's double-blind, placebo-controlled Phase 2 clinical trial has completed enrollment of 100 patients with intervertebral disc disease
- Primary endpoint for this study is safety, secondary efficacy endpoints include reduction in low back pain and improvement in function and quality of life that is sustained for six months
- Results from this trial are expected mid-2013, and, if successful, would underpin progression of this indication to Phase 3.

mesoblast

III. Products Delivered Locally For Cardiovascular Diseases

- The lead product in Mesoblast's alliance with Teva Pharmaceutical Industries Ltd is for congestive heart failure (CHF), the number one cause of hospitalization in the industrialized world

- In Mesoblast's Phase 2 trial for CHF, patients treated with a single intra-cardiac injection of the highest dose of MPCs have to date had no heart failure hospitalization events nor cardiac-related deaths over a mean follow-up period approaching three years

- On the basis of these results, Teva and Mesoblast have been working closely together and have had meetings with both the FDA and the European Medicines Association (EMA) on a Phase 3 trial design for congestive heart failure

- The trial is expected to commence during 2013 and to have an early interim analysis for evidence of efficacy

- A second indication in the alliance is the use of MPCs for prevention of CHF after an acute myocardial infarction, or heart attack. A placebo-controlled Phase 2 trial for this indication is underway in Europe and Australia.

mesoblast

Other Products – Eye Diseases and Bone Marrow Transplantation

Developing stem cell therapeutic product for treating various vascular and inflammatory diseases of the eye including wet and dry age-related macular degeneration (AMD)

- Wet and dry AMD are the major causes of blindness in the elderly
- Phase 2 trial wet AMD study currently enrolling patients at sites in Singapore and Australia

Developing stem cell therapeutic product to improve bone marrow transplant outcomes and provide a therapy for patients who cannot find a donor and may otherwise die

- Ongoing Phase 3 clinical trial using MPCs to expand hematopoietic precursors from cord blood for transplantation in cancer patients whose bone marrow has been destroyed by high dose chemotherapy
- Aim is to increase 3-4 fold the number of unrelated donor transplants.

mesoblast

The Year Ahead, What We Expect:

- Clinical results of Phase 2 trial in intervertebral disc repair
- Clinical results of Phase 2 trial in early type 2 diabetes
- Expand focus on intravenous product franchise with additional Phase 2 trials

  - diabetic kidney disease
  - rheumatoid arthritis
  - lung diseases

- Commencement of Phase 3 trial for congestive heart failure involving an early interim analysis to evaluate evidence of efficacy
- Commencement of Phase 3 trial for lumbar spinal fusion
- Additional partnering opportunities – optimal timing.

mesoblast

mesoblast

the regenerative medicine company

Leading the world in novel adult stem cell therapies

Melbourne, Australia
February 2013