mesoblast

the regenerative medicine company

Leading the world in novel adult stem cell therapies

JP Morgan Healthcare Conference January 2013

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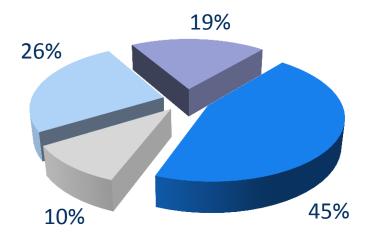
Corporate overview



Shareholder value and ownership

Market valuation	
Issued shares	287 million
Current share price*	\$5.24
Market capitalization (approx)	circa \$1.58 billion

Shareholder ownership



- Institutions/sophisticatedilnvestors
- Retail investors
- Management
- Strategic Investors



Corporate partnerships manage execution risk – Teva alliance

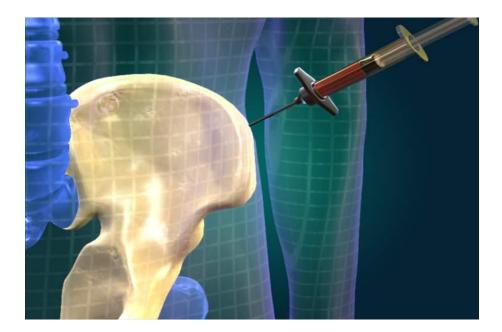
- Partnership focus on cardiovascular, neurologic diseases
- Lead product for congestive heart failure number 1 cause of hospitalization in industrialized world
- Provides Phase 3 clinical and regulatory expertise
- Provides funding for partnered programs
- Provides global distribution strength
- Allows Mesoblast to focus on manufacturing optimization



Corporate partnerships manage execution risk – Lonza alliance

- Lonza partnership provides global process development and manufacturing capability
- Exclusive access to state-of-the-art Lonza Singapore facility for allogeneic cell manufacture
- 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





Mesenchymal Precursor Cell (MPC) technology



Our proprietary MPC technology platform

- 1. Patented adult stem cell technology platform for Stro-1/Stro-3 cells
- 2. Highly purified populations of earliest precursors of mesenchymal lineage cells present in multiple tissue sites, e.g. bone marrow, adipose, dental pulp
- 3. Scientific advantages based on high degree of potency and effectiveness of this purified cell type across multiple disease targets
- 4. Commercial advantages derive from high degree of expansion potential and relative non-immunogenicity...allogeneic cell therapy



Leveraging our proprietary MPC technology platform

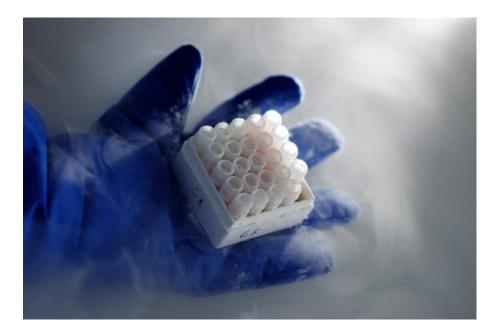
- Products specifically target major medical conditions where proprietary technology offers unique scientific and clinical advantages
- Multiple products developed in parallel to increase probability of success
- Strong cash position enables simultaneous product development
- Probability of success enhanced through strategic partnerships
- Potential to deliver significant and sustainable revenues via either direct product sales or through profitable manufacturing operations



MPC technology platform delivers product diversity

- 1. Products in partnership with Teva, primarily in cardiovascular and neurological diseases
- 2. Products for intravenous delivery in type 2 diabetes and its complications including kidney disease
- 3. Products delivered intravenously for immunologic/inflammatory conditions, such as lung and joint diseases
- 4. Products locally administered for orthopedic diseases of the spine, and vascular and inflammatory eye conditions





Product manufacturing



Product manufacturing strategy

Our objectives are to ensure:

- Regulatory compliance with best practice
- Product delineation supporting partnering/reimbursement
- New product development
- Commercial scale-up
- Capacity for commercial product supply
- Reduced COGS



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

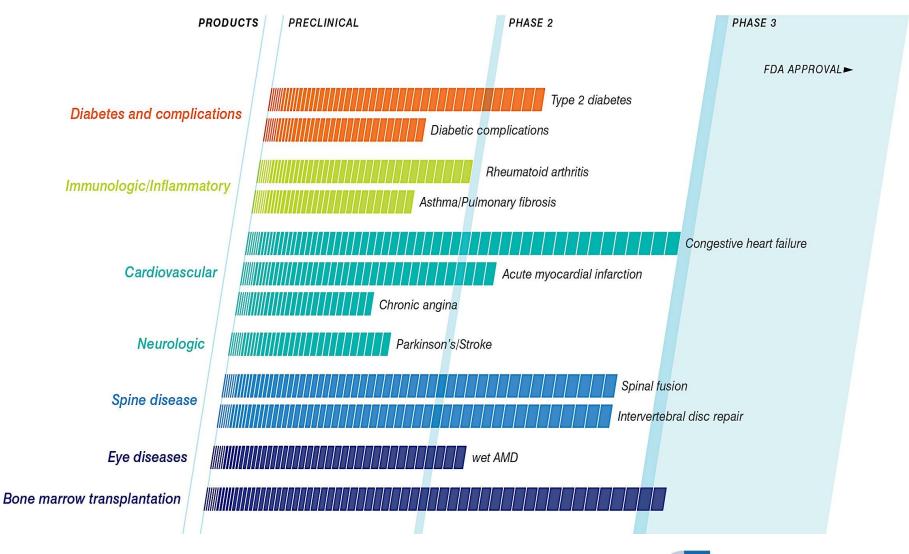




Product pipeline



Platform delivers multi-product pipeline





Products for intravenous administration

Intravenous products to treat prevalent systemic disorders affecting the metabolic, inflammatory and immune systems

- type 2 early diabetes
- kidney failure and cardiovascular complications
- liver fibrosis

Inflammatory/immune mediated diseases

- inflammatory joint diseases rheumatoid arthritis
- Iung diseases asthma, pulmonary fibrosis

Intravenous formulation of MPCs can be delivered once or multiple times for disorders that affect multiple organs



Intravenous delivery – Type 2 diabetes

- Randomized, placebo-controlled Phase 2 trial in 60 patients with type 2 diabetes actively recruiting under FDA guidance
- Patients evaluated over 12 weeks for blood glucose control and inflammatory markers such as C-reactive protein (C-RP)
- Objective to find optimal dose for both glucose control and reduction in inflammation parameters

Trial will set foundation for evaluating MPCs in treating patients with advanced diabetes and life-threatening complications such as renal failure and cardiovascular disease



Intravenous delivery – renal complications of diabetes

- Plan to evaluate whether single dose of MPCs can stabilize or reverse end-stage kidney disease
- Nearly 10% annual rate of cardiovascular disease and death in diabetic patients with end-stage kidney disease
- Non-human primate study showed circulating C-RP levels significantly reduced after single MPC dose (C-RP is major predictor of cardiovascular risk in diabetes)

Plan to evaluate whether intravenous MPC therapy has potential to offer cardioprotective and renal benefits in these patients



Intravenous delivery – immune-mediated diseases

- Preclinical data indicate MPCs have immunomodulatory properties
- Single intravenous injection may provide sustained benefits for immunemediated diseases
- Mechanism of action (MOA) may be unique, shutting down multiple cytokine pathways simultaneously:
 - TNF-alpha, IL-6, IL-17 are mediators that drive autoimmune diseases such as rheumatoid arthritis, Crohn's disease, multiple sclerosis
 - existing treatments require chronic administrations; may cause unacceptable infectious adverse events

Initial targets are inflammatory joint and lung diseases

Randomized, placebo-controlled Phase 2 trials of MPCs for patients with RA planned as either first line treatment or rescue after failure with other biologics



Products for local administration – cardiovascular

With Teva, developing therapies for cardiovascular diseases including congestive heart failure (CHF) and acute myocardial infarction (AMI)

- Phase 2 trial for CHF showed patients treated with single intra-cardiac injection of highest dose of MPCs have had no hospitalization for decompensated heart failure or cardiac-related deaths over nearly 3 years of follow-up
- Teva and Mesoblast met with FDA and EMA to discuss aligned Phase 3 trial with endpoint of reduction in hospitalization and death
- Teva and Mesoblast are working closely on a detailed Phase 3 trial design involving an early interim analysis to evaluate evidence of efficacy
- Phase 2 AMI trial ongoing in Europe and Australia
- Additional potential areas include chronic refractory angina



Products for local administration – spine disease

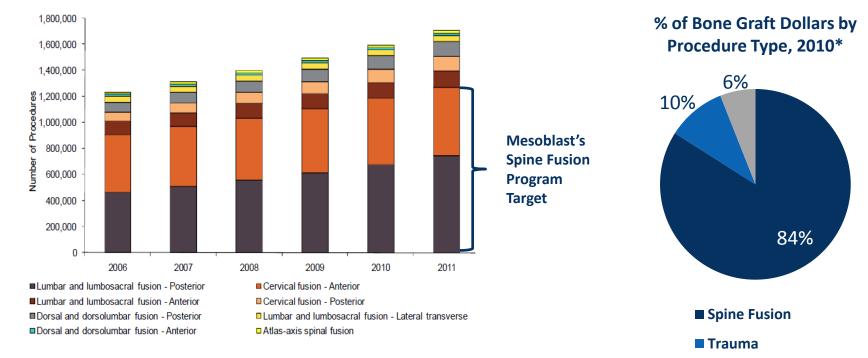
Diseases of the spine represent largest growing market segment in orthopedics

- Spinal fusion product for patients with advanced disc degeneration who need surgery
 - Phase 2 lumbar spinal fusion trial completed enrollment
 - 12-month follow-up results for lumbar fusion
- Larger market for restoration of early lumbar disc damage
 - Phase 2 study completed enrollment of 100 patients with intervertebral disc disease
 - Results expected mid 2013

Spinal franchise will likely be optimized with one or more strategic partners, leveraging distribution and market strengths



Why Spine Fusion for Bone Repair Indication Target?



Global Spine Fusion Procedures

Spinal Procedures - Global2011Lumbar Fusion1,043,803Cervical Fusion662,695Global Total1,706,498

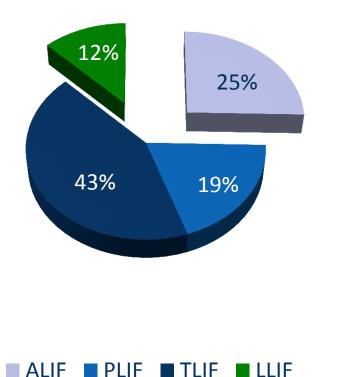


Recon/Joint Replacement



Lumbar Fusion Procedures by Surgical Approach

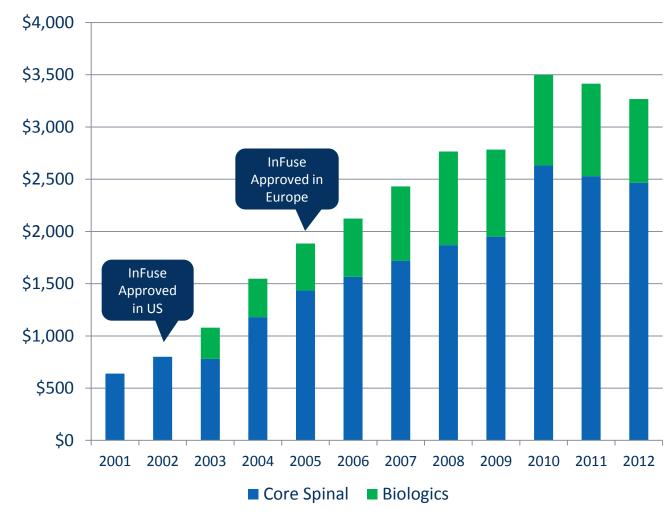
Surgical Approaches of 2012 Lumbar Fusion Procedures



- Mesoblast's Phase 2 lumbar fusion study included the posterior approaches (PLIF & TLIF) that account for 62% of lumbar fusion procedures
- Almost all lumbar fusions can be performed using the posterior approaches
- Some pathologies can not be addressed through ALIF approach alone
- Lateral approach typically limited to L4-L5 levels and above as the iliac crest blocks lateral access to the L5-S1 disc



Medtronic's InFuse/BMP-2 as a Precedent



- Medtronic's sales of biologics, predominantly InFuse rose
 >20% year over year from
 2003 to 2008
- Sales of InFuse have remained steady since 2008 at >\$800M until slight drop in last year
- Since introduction of InFuse,
 Medtronic core spinal sales
 (i.e. hardware) have increased
 over 300%



Mesoblast's Spine Fusion Clinical Program

Posterolateral Fusion

- first study using Mesoblast's allogeneic MPCs unilaterally in posterior lumbar gutter, comparing with bone autograft
- three-year study follow-up completed 2012
- safety and efficacy supported expansion into more clinically-relevant surgical approaches, in attempt to eliminate need for bone autograft and its associated risks (hip pain, infection, blood loss)

Posterior/Transforaminal Lumbar Interbody Fusion

- study started in 2009, 12 month follow-up results reported January 2013
- commercially focused indication in largest fusion surgical approaches, PLIF & TLIF procedures
- successful precedent in Medtronic's InFuse/BMP-2 product
 - Sales of InFuse peaked at almost \$1 billion, but declining
 - Published safety issues
 - Used primarily off-label in posterior approach procedures instead of approved anterior approach

Strong clinician and patient demand for a spine fusion product with improved safety profile



Lumbar Fusion Phase 2 Clinical Trial

Enrollment & 1 Year Follow-up for End of Phase 2 Complete

- Phase 2 trial under IND clearance
- Multi-center, randomized, two-dose comparator trial
- Trial conducted across 5 US sites
- 1 & 2 Level TLIF or PLIF
- 24 treated patients, now completed one year follow-up
 - Randomized to one of three groups: bone autograft, 25M or 75M MPCs on carrier graft
 - PEEK cage and pedicle screws/posterior hardware
 - Primary endpoint safety of each MPC dose
 - Exploratory efficacy endpoints:

radiographic fusion improvement in back and leg pain improvement in function and disability procedure-related comorbidity

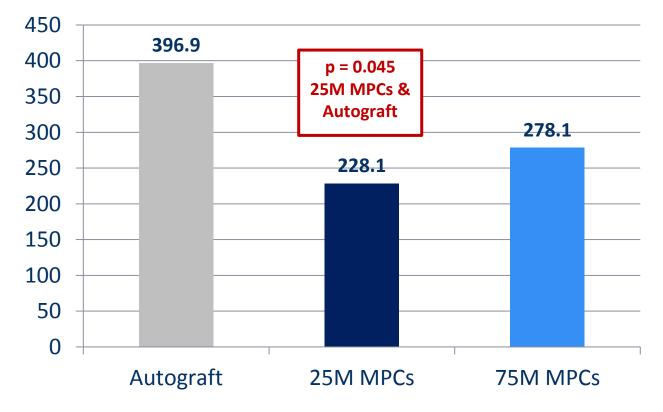


Evaluation of MPC Treatment Safety in Lumbar Fusion

- The safety profiles of the autograft control and two cell treated groups were similar
- MPCs were well tolerated, no cell-related serious adverse events
- No heterotopic bone formation was seen in any of the groups
- 1/8 autograft patients and 1/16 MPC treated patients developed de novo low-titer anti-HLA antibodies, with no associated clinical manifestations



Reduced average blood loss in patients treated with MPCs compared to Autograft

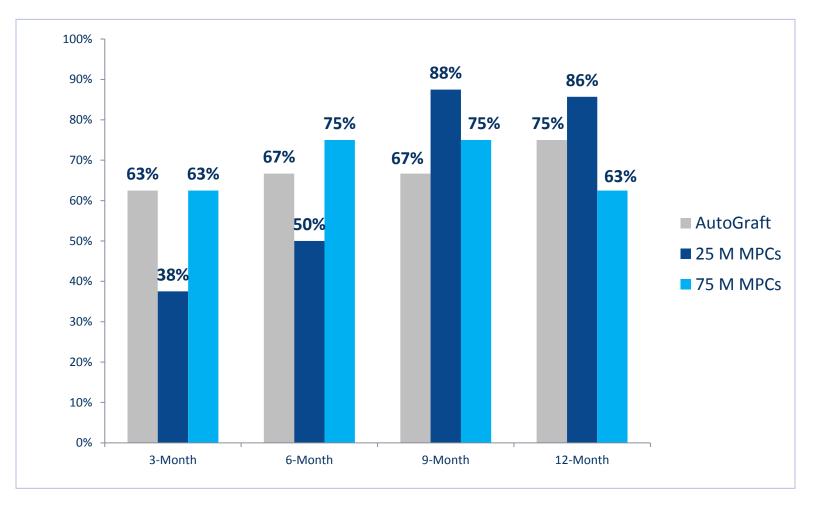


Average Blood Loss (mL)

25M and 75M MPC treated groups had a 43% and 30% reduction in average blood loss compared to Autograft

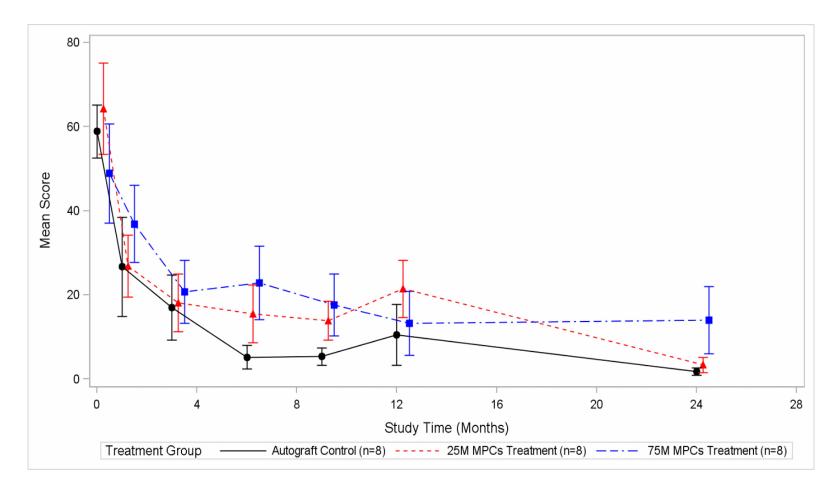


MPC Treated Patients Achieved Similar Fusion Success to the "Gold Standard", Bone Autograft



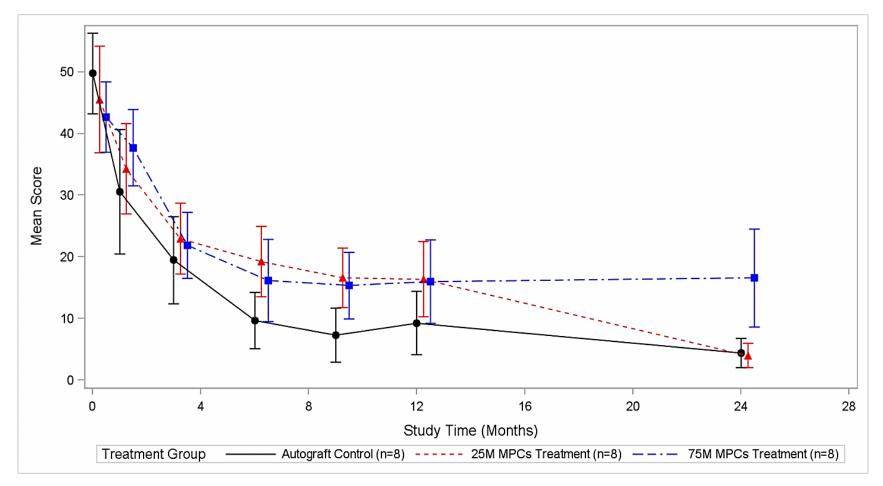


MPC and autograft implanted patients achieved significant back pain relief compared to baseline





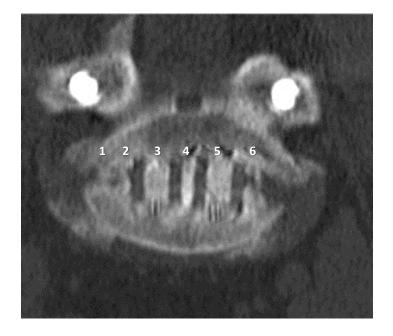
MPC and autograft implanted patients achieved significant functional improvement (Oswestry Score) compared to baseline

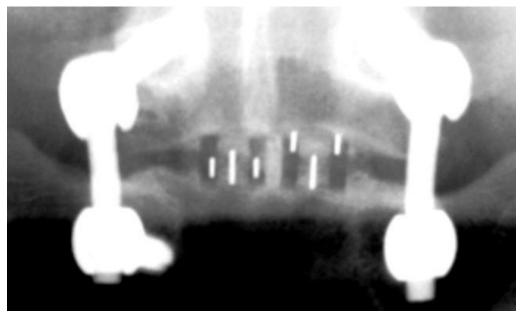




Lumbar Fusion Patient Implanted with MPCs Showing Robust Bone Formation and Fusion

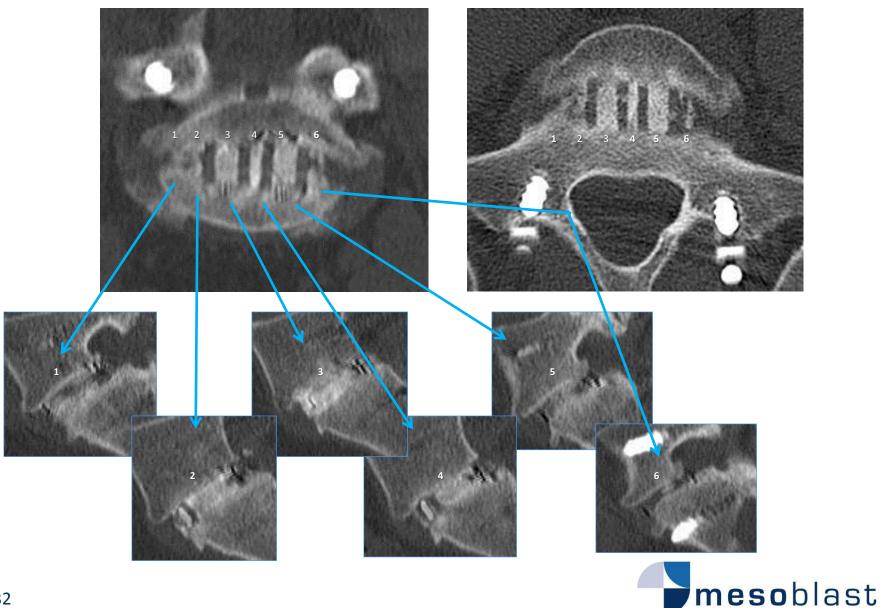
CT & X-Ray at 3 months Follow-up







Lumbar Fusion Patient @ 3 months with robust bone formation



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



The year ahead, what we expect:

- 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
- Clinical results in Phase 2 trials with early type 2 diabetes and intervertebral disc repair
- Ongoing Phase 2 trial for AMI and Phase 3 for BMT
- Expand focus on intravenous product franchise with commencement of Phase 2 trials for
 - diabetic kidney disease
 - rheumatoid arthritis
 - lung diseases
- Additional partnering opportunities optimal timing



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