
mesoblast
the regenerative medicine company



2013 Financial Year Results

29 August 2013

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Financial Results Snapshot

Results	2013	2012
Total revenue & other income	34.7M	38.3M
Operating expenses		
R&D	43.1M	36.9M
Manufacturing	20.9M	22.0M
Management	30.7M	28.1M
Income tax expense	1.7M	22.4M
(Losses) / profit after tax	(61.7M)	(71.1M)
EPS basic – cents per share	(21.06)	(25.15)
EPS diluted – cents per share	(21.06)	(25.15)
Cash	315M	206M

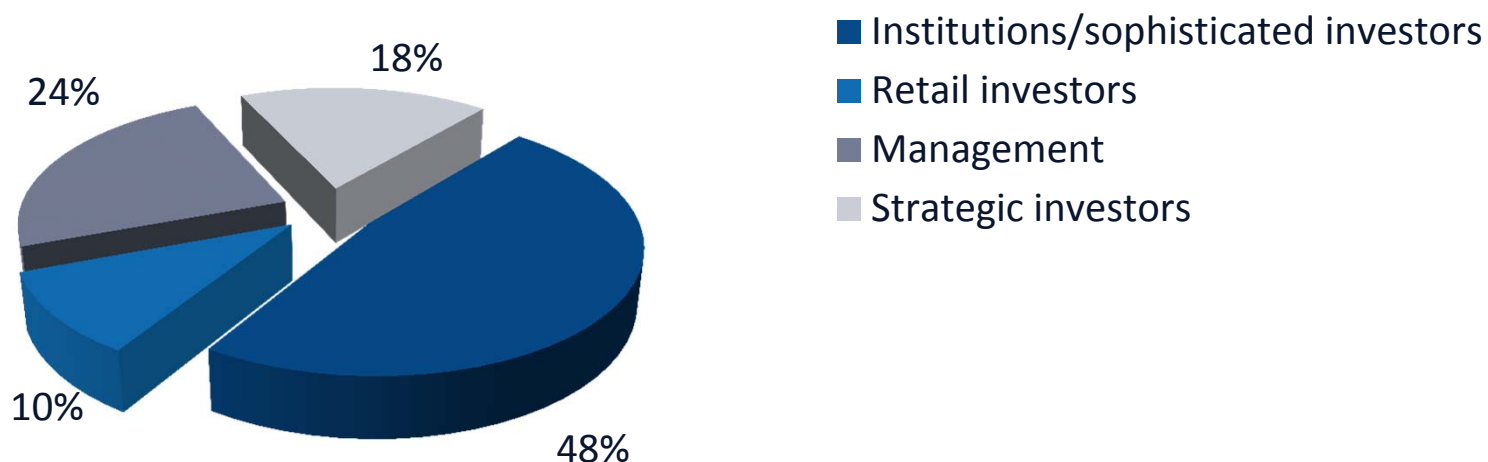
Financial Results Snapshot

Total revenue and other income	2013	2012
Revenue from continuing operations		
Commercialization revenue	18.3M	27.7M
Interest revenue	10.5M	10.5M
Other income		
Research and development tax incentive	5.9M	-
Government grants	-	0.1M
Total	34.7M	38.3M

Shareholder value and ownership

Market valuation	
Issued shares	316.5 million
Current share price (market close, August 28 2013)	\$5.62
Market capitalization, circa	\$1.78 billion
Cash reserves	\$315.3 million

Shareholder ownership



Strategic focus

Mesoblast's corporate strategy is to:

- leverage proprietary cell-based and complementary biologic technologies to develop products for unmet medical needs;
- bring multiple products to market within a parallel timeframe;
- underpin our future financial growth through investing in manufacturing operations; and
- enhance the likelihood of commercial success through strategic partnerships

Strong Cash Position Enables Execution Of Late-Stage Clinical Trials

- Completed \$170 million financing from targeted global financial investors

Total working capital of \$315.3 million will be used to

- execute additional Phase 3 trials
- broaden our clinical development programs in diseases of inflammation and immunity
- access complementary technologies for product diversification, and
- ramp up commercial manufacturing operations

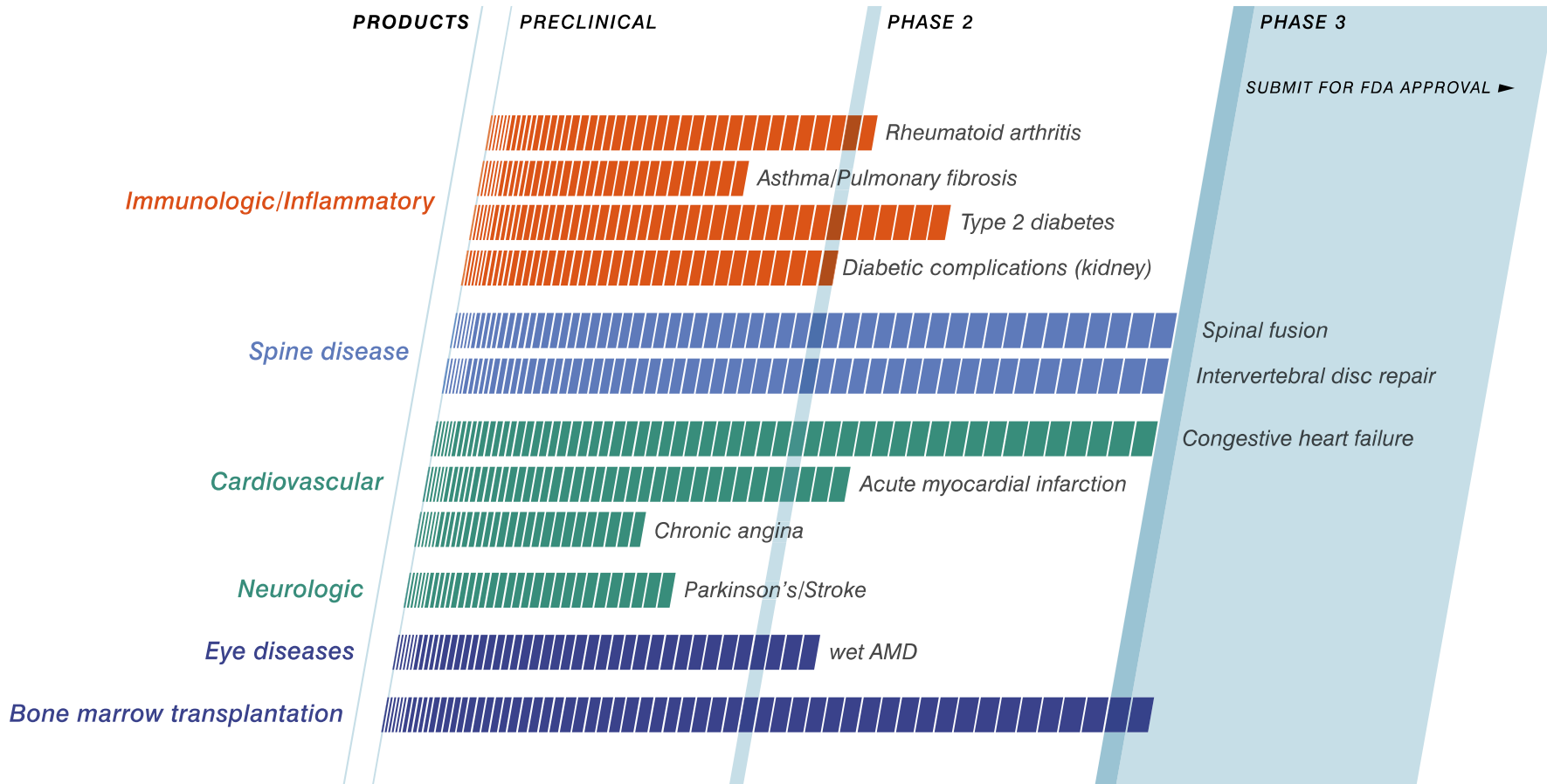
Mechanisms of Action (MOA) Drive Product Development

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.

Cell-based Technologies Deliver Multiple Product Pipeline



Major accomplishments – immune/inflammatory disorders treated intravenously with MPCs

Diabetes

- Completed enrollment of 60-patient Phase 2 trial evaluating single intravenous MPC injection in patients with early type 2 diabetes not adequately controlled on oral glucose-reducing agents
- Patients evaluated over 12 weeks for effectiveness of a single intravenous MPC dose on changes in glucose control, and various inflammatory markers, including C-reactive protein

Diabetic kidney disease

- Received approvals from Australian ethics committees to commence Phase 2 trial evaluating single infusion of MPCs in patients with type 2 diabetes and advanced kidney disease, or diabetic nephropathy

Rheumatoid arthritis (RA)

- Received FDA clearance and commenced Phase 2 program to evaluate intravenously injected MPCs to rescue RA biologic failures
- Results to guide future direction of the RA program

Major accomplishments – spinal diseases

Spinal fusion product

- Phase 2 trial in lumbar fusion demonstrated equivalence of MPC treatment at 12 months with autogenous hip autograft in terms of radiographic fusion, pain reduction, and improvement in function
- Data are being used in discussions with FDA regarding Phase 3 trial
- If successful, MPC will eliminate need for autograft and its risk of pain, infection, and blood loss at the harvest site
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Degenerative disc repair product

- Obtained positive 6-month results in pre-specified interim results of first 50 patients
- Analysis showed single low-dose injection of MPCs resulted in significantly greater reduction in low back pain, significantly greater improvement in function, and significantly greater treatment success compared with controls
- Full results from 100-patient disc repair study expected to be available in 2H 2013, and may lead to a Phase 3 trial 1H 2014

Major accomplishments – strategic partnerships

- Phase 2 trial for congestive heart failure closed as per protocol after all patients completed three years of follow-up. The complete dataset showed that patients treated with the highest MPC dose have not experienced any hospitalizations for decompensated heart failure nor any cardiac-related deaths over the three year period.
- Worked closely with **Teva** Pharmaceutical Industries Ltd to finalize the Phase 3 congestive heart failure protocol and associated documentation for regulatory submission to the FDA.
- Worked with **Lonza** to ensure commercial scale-up and supply, product delineation, and COGS reductions.
- Expanded clinical manufacturing operations to Singapore plant, in addition to continuing operations at the US plant, to offset single site dependence and increase capacity.
- Obtained FDA agreement that clinical manufacturing of cell products at both Singapore and US plants meet Phase 3 trial requirements, including the congestive heart failure trial.

Major accomplishments – intellectual property

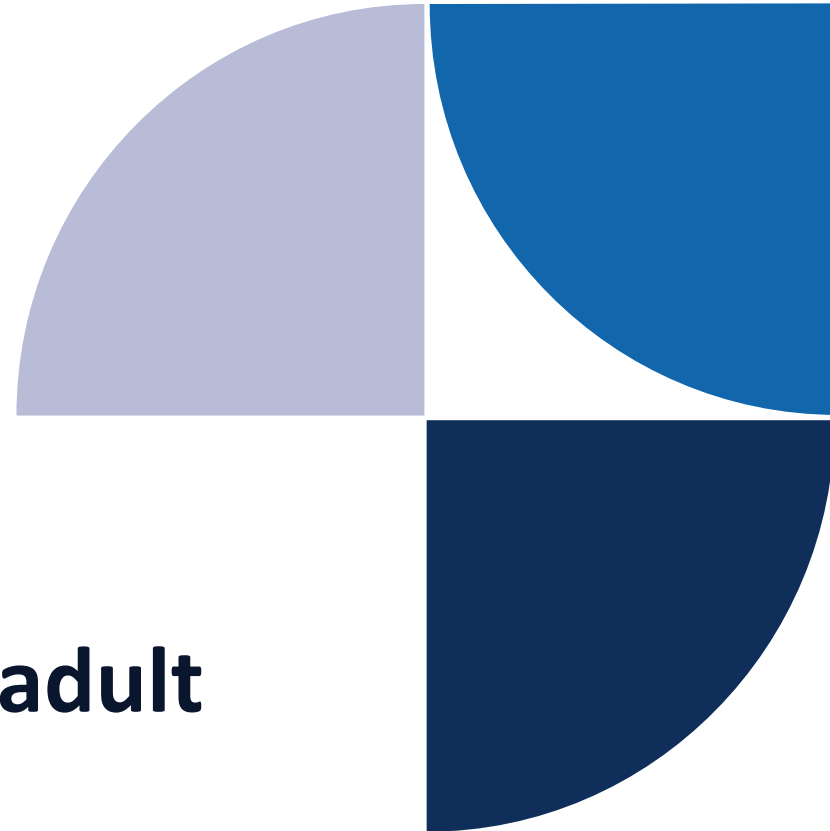
- Significantly expanded patent portfolio to support long-term business goals of protecting our products as we broaden our access to and penetration of global markets
- Key patents granted by the US Patent and Trademark Office and the State Intellectual Property Office of the People’s Republic of China
- Key patent granted by the Japanese Patent Office, providing exclusive commercial rights in Japan through September 2025 to all compositions-of-matter and uses of MPC technology platform

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 a Phase 3 trial for spinal fusion
- Results of full dataset for Phase 2 trial in intervertebral disc repair
- Results of Phase 2 trial in early type 2 diabetes
- Continued recruitment in Phase 3 cord blood trial
- Continued recruitment in Phase 2 trials for
 - Diabetic Nephropathy,
 - Rheumatoid Arthritis
 - Macular Degeneration
- Expansion of inflammatory conditions being targeted, including lung diseases
- Continuing reassessment of priorities and focus on broadening opportunities
- Additional partnering activities – optimal timing

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**Leading the world in adult
stem cell therapies**
