

Half-Year Report 31 December 2013

Mesoblast Limited ABN: 68 109 431 870 And Controlled Entities (Mesoblast Group)

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## Directors' Report

The Board of Directors of Mesoblast Group has resolved to submit the following half-year report of the Company and its subsidiaries for the half-year ended 31 December 2013. In order to comply with the provisions of the *Corporations Act 2001*, the directors report the following information:

#### **DIRECTORS**

Directors of the Company in office at any time during or since the end of the half-year (unless specified) were:

Name	Position
Silviu Itescu	Executive Director
Brian Jamieson	Chairman
Donal O'Dwyer	Non-executive Director, Chair of Nomination and Remuneration Committee
Eric Rose	Non-executive Director, Chair of Science and Technology Commitee
Michael Spooner	Non-executive Director, Chair of Audit and Risk Committee
Dr Ben-Zion Weiner	Non-executive Director

#### **Principal Activities**

#### **Corporate Strategy**

To accomplish our corporate strategy of bringing multiple products to market within a parallel timeframe, we rely on our financial strength, robust manufacturing operations, delivery of our clinical programs, and the formation of strategic partnerships to enhance commercial success. In addition, we continue to strengthen our global intellectual property portfolio which underpins the intrinsic value of our key technologies and ultimately our future products.

#### **Key Technologies**

Mesoblast's cell-based core technologies include its highly purified, immunoselected Mesenchymal Precursor Cells (MPCs), culture-expanded Mesenchymal Stem Cells (MSCs), Dental Pulp Stem Cells (DPSCs), and expanded Hematopoietic Stem Cells (HSCs).

Highly purified, immunoselected MPCs and the cultured MSCs share very important technical characteristics – both populations can be expanded in large numbers in culture, are well tolerated when used allogeneically in unrelated recipients, and may differentiate to greater or lesser degrees into bone, fat and cartilage.

In addition, these cell types release a series of factors which may act on target tissues to induce blood vessel formation, reduce fibrous scar tissue, improve bone and cartilage growth, and modulate the key elements of the immune system, including monocytes and T cells.

Mesoblast's culture-expanded MSC products are being evaluated for induction of rapid clinical responses following frequent multi-dose administration systemically. Highly purified, immunoselected MPC products are being evaluated for more durable clinical outcomes following single-dose or intermittent administration locally or systemically.

#### **Core Therapeutic Areas**

Mesoblast's investigational product pipeline targets four distinct and substantial market areas of unmet medical need using its mesenchymal lineage cells:

- 1. Intravenously-delivered products for systemic inflammatory and immune-mediated diseases
- Cardiac and vascular diseases treated with local and systemic application
- 3. Orthopedic diseases of the spine treated with local administration
- 4. Oncology conditions associated with bone marrow transplantation

Over the reporting period, progression of the Company's clinical trial program and strategic acquisition of the MSC assets presented Mesoblast with latestage developmental products in all four of its core therapeutic areas.

#### **Review of Operations**

#### 2014 Financial Year Highlights

- Obtained positive results at 12 months in a 100 patient Phase 2 trial for lumbar intervertebral disc repair evaluating safety and efficacy of MPCs.
- United States Food and Drug Administration (FDA)
  clearance of Phase 3 trial of MPCs for chronic
  congestive heart failure within the minimum 30-day
  period. This 1,700 patient trial is being funded and
  sponsored by our clinical and commercial development
  partner, Teva Pharmaceutical Industries Ltd., with
  recruitment across multiple United States sites.
- Announced positive topline efficacy results from Phase 2 trial of MPCs in patients with type 2 diabetes with a mean disease duration of 10 years and inadequate glucose control by Metformin and other oral glucose-lowering agents.
- Commenced a Phase 2 trial in Australia to evaluate the effects over three months of a single infusion of one of two MPC doses in 30 patients with type 2 diabetes and end stage kidney disease.

- Acquired culture-expanded MSC assets from Osiris Therapeutics resulting in broadening of market opportunities with additional Phase 3 programs, accelerated commercial product launch, and strengthening of leadership position in regenerative medicine.
- Mesoblast collaborator, JCR Pharmaceuticals, is planning to submit for registration in Japan, MSCs in the treatment of steroid-refractory graft versus host disease in children and adults after bone marrow transplant.
- Strengthened MPC intellectual property estate and acquired culture-expanded MSC intellectual property, complementing and extending Mesoblast's existing patent estate. Key patents for MPCs were also granted in Europe, Japan and China.
- Optimized manufacturing operations at Singapore and United States plants.
- Ongoing optimization of bioprocessing to support commercial product scale-up.

## Acquisition of Culture-Expanded Mesenchymal Stem Cell Assets

In October 2013, Mesoblast acquired the culture-expanded MSC assets of Osiris Therapeutics, with consequent strategic and financial benefits. The MSC product candidates represent first generation stem cell products and are expected to provide Mesoblast with an earlier entry to market and product revenue streams.

Overall, Mesoblast's clinical product pipeline derives from the Company's proprietary mesenchymal cell lineage technology platforms. Highly purified, immunoselected MPCs are being evaluated for more durable clinical outcomes following single-dose or intermittent administration locally or systemically. Products using MSCs are being developed to induce rapid clinical responses following frequent repeat-dose administration systemically.

The acquired mature clinical development pipeline using MSCs targeting Crohn's disease and acute Graft Versus Host Disease (GVHD) complement Mesoblast's core therapeutic areas of inflammatory diseases and oncology-related products. Importantly, these programs broaden Mesoblast's Phase 3-ready products and provide extensive, long-term clinical data from more than 1,500 patients treated with cultured MSCs, including safety, efficacy and repeat dosing data.

#### Strengthening of Intellectual Property

The intellectual property portfolio was significantly strengthened with the acquisition of the culture-expanded MSC assets. Mesoblast now has ownership of or exclusive rights to over 60 mesenchymal precursor or stem cell patent families and approximately 140 granted patents in key markets including the United States, Europe, Japan and China which provide major commercial advantages and long-term protection.

Most recently, Mesoblast was granted a key patent by the European Patent Office covering the use of MPCs for the treatment of cardiac and vascular conditions, including acute myocardial infarction, congestive heart failure, angina, peripheral arterial disease, and cerebrovascular stroke. The patent provides the Company with exclusive commercial rights in Europe initially through to 29 March 2024, with potential for extension based on duration of clinical development.

Mesoblast's patent position in Japan was further strengthened during the reporting period by the granting of a composition-of-matter patent which confers exclusive commercial rights for its MPC technology platform irrespective of the MPC tissue source, including bone marrow, adipose, placenta, umbilical cord and dental pulp.

#### **Manufacturing Operations**

Using well characterized cellular populations has facilitated proprietary manufacturing processes which promotes reproducibility and batch to batch consistency. The Company's manufacturing activities are structured to meet stringent criteria set by regulatory agencies in each jurisdiction the Company operates.

Our manufacturing alliance with one of the world's leading biologics manufacturers, Lonza, supports our overall corporate strategy. This alliance aims to ensure that product supply will meet anticipated market needs across major geographical jurisdictions, and to facilitate a sustainable cost-of-goods structure that will maximize return on investment.

Mesoblast is in the process of prioritising commercial applications of first generation MSC products and second generation MPC products. Manufacturing strategies moving forward will take into account these priorities for product delineation.

During the half year, Mesoblast has continued to optimize both its existing manufacturing processes and new bioprocessing technologies for future commercial product inventory and cost of goods reductions.

#### **Clinical Pipeline Progress**

#### 1. Inflammatory and immune-mediated diseases

#### Crohn's disease

Mesoblast has an advanced clinical program to develop Prochymal®, (remestemcel-L, human mesenchymal stem cells for intravenous infusion), aiming to induce early disease remission in patients with refractory moderate to severe Crohn's disease.

Crohn's disease is a chronic, life-long condition with relapsing inflammation of the gastrointestinal tract. The immune system is centrally involved in disease pathogenesis, particularly a certain type of proinflammatory T cell population called Th17 cells, which are counterbalanced by FoxP3 regulatory T cells. Mesenchymal lineage precursor and stem cells have been shown to reduce activity of Th 17 cells and increase activity of FoxP3 regulatory T cells.

A Phase 3 multi-centered, double-blind, randomized, placebo-controlled trial is evaluating the safety and efficacy of Prochymal® in moderate to severe Crohn's disease in patients who are refractory to steroid, immunosuppressant and biologic therapy. The primary endpoint is the proportion of patients experiencing disease remission within 28 days of treatment with Prochymal®, compared to those patients receiving placebo.

The trial successfully met a pre-defined interim analysis for futility undertaken after 207 patients were enrolled. An optimal dose of Prochymal® was determined from the interim analysis data and the trial is being completed using this dose.

#### Type 2 diabetes

Type 2 diabetes is a disease of excessive weight and dietary overload, with these inciting factors inducing a state of general inflammation, particularly affecting the fat tissues where there is increased production of pro-inflammatory cytokines such as IL-6 and TNF-alpha by both inflammatory monocytes, called M1 type monocytes, and by fat cells or adipocytes. These cytokines impair the ability of the fat tissues and of the liver to respond normally to insulin. Mesenchymal lineage stem cells have been shown to secrete factors which polarize pro-inflammatory M1 type monocytes to an anti-inflammatory M2 type, which is characterized by secretion of anti-inflammatory cytokines such as IL-10.

In December 2013, the Company announced topline results from its Phase 2 trial of MPCs in patients with inadequately controlled type 2 diabetes. The trial evaluated the effects of a single intravenous infusion of 0.3, 1.0 or 2.0 million MPCs/kg or placebo over 12 weeks in 61 patients with a mean diabetes duration of 10 years and inadequate glucose control by Metformin and other oral glucose-lowering agents.

Key findings included a dose dependent reduction in HbA1c at 8-12 weeks after a single MPC infusion, a significant increase in the number of patients who achieved a target HbA1c <7% at week 12 following a single infusion of the highest MPC dose compared with placebo, and no treatment-related adverse events.

The results suggest that the immunomodulatory effects of a single MPC injection may improve glucose control on top of other glucose-lowering agents for as long as three months in type 2 diabetes. This sets the foundation for further investigation to evaluate whether a single MPC injection can have an immunomodulatory effect on the kidney and other complications of diabetes, and thus address the major therapeutic gaps in diabetes care.

#### End-stage kidney disease

Despite various therapies which are effective for reducing blood glucose levels, such as Metformin, after about 15-20 years from first being diagnosed with type 2 diabetes, many patients develop significant damage to a range of organs, including kidney and liver disease. These complications are thought to result from a continued underlying state of inflammation as well as dysfunction of small blood vessels.

The first end-stage organ complication of type 2 diabetes being evaluated by Mesoblast is end-stage kidney disease or diabetic nephropathy. Over the reporting period, patient recruitment continued in a randomized, placebo-controlled Phase 2 trial being undertaken in Australia to evaluate the effects over three months of a single infusion of one of two MPC doses in 60 patients with type 2 diabetes and end stage kidney disease.

#### Rheumatoid arthritis

Rheumatoid arthritis is a chronic systemic disease characterized by progressive joint deformity and joint destruction driven by synovial inflammation and hyperplasia in which multiple cytokines play central pathogenic roles. MPCs have been shown to have a broad immunomodulatory effect on inflammation and autoimmunity, simultaneously inhibiting effector T cells, inducing regulatory T cells, and polarizing pro-inflammatory monocytes to an anti-inflammatory type.

After clearance from the FDA, Mesoblast commenced a Phase 2 clinical trial evaluating a single intravenous infusion of its MPCs for the treatment of active rheumatoid arthritis in patients who have failed at least one tumor necrosis factor (TNF) -alpha inhibitor.

The randomized, double-blind placebo-controlled dose escalation study evaluating the safety, tolerability and effectiveness of a single intravenous infusion of two MPC dose levels with recruitment of the 48 subjects is well underway.

#### 2. Cardiac and vascular diseases

## New York Heart Association (NYHA) Class II/III heart failure

In October 2013, the FDA cleared the Investigational New Drug filing submitted by Mesoblast's commercialization partner, Teva Pharmaceutical Industries, to commence a Phase 3 trial in patients with chronic congestive heart failure, who are classified as either NYHA class II or class III disease and have an ejection fraction of ≤40%. Sites in the United States are being initiated and patient recruitment has commenced.

The MPC dose for the Phase 3 trial was chosen on the basis of results from a 60-patient Phase 2 trial which showed that heart failure patients treated with the 150 million MPC dose did not experience any heart failure-related Major Adverse Cardiac Events (HF-MACE), over the three-year follow-up period compared with an HF-MACE incidence of approximately 30 per cent for the control group over the same period. Moreover this dose had the greatest beneficial effect on surrogate parameters of left ventricular dysfunction such as end systolic and end diastolic volumes.

#### NYHA Class IV heart failure

In November 2013, further evidence for the strength of Mesoblast's cardiovascular products was provided by the positive results obtained in a Phase 2 clinical trial which assessed the safety and efficacy of Mesoblast's MPCs in NYHA class IV congestive heart failure patients receiving a left ventricular assist device. A multi-center team of researchers within the United States National Institutes of Health-funded Cardiothoracic Surgical Trials Network reported that a single MPC injection of 25 million allogeneic MPCs resulted in improved cardiac function and survival at the trial's primary 90-day endpoint. The results were presented at the American Heart Association Scientific Sessions 2013.

Further studies are expected to be conducted in this important group of end-stage heart failure patients with limited options.

#### Heart attack

Mesoblast is developing mesenchymal cell lineage products for use in the acute myocardial infarction setting with a view to preventing the onset of heart failure complicating a large infarct. Through the acquisition of the Osiris ceMSC assets, Mesoblast can now evaluate outcomes of mesenchymal lineage cells delivered by various routes after a heart attack.

Phase 2 clinical trials using catheter-delivered MPCs and intravenously injected MSCs to address cardiac function and reduce the likelihood of heart failure following an acute myocardial infarct are ongoing in Europe and the United States.

#### Ischemic Stroke

In November 2013, preclinical trial data demonstrating that MPCs induced improvement in the functional recovery in a rat model with ischemic stroke were presented at the Neuroscience 2013 conference in the United States. The preclinical study showed that a single intravenous injection of human MPCs significantly enhanced sensorimotor recovery when administered up to seven days after an ischemic stroke in rats. In a sub-study, MPCs were shown by functional magnetic resonance imaging to have increased neuronal activity and reduced the volume of infarct tissue. Together, these results suggest that MPCs have the potential to be used within a broad and clinically meaningful therapeutic time window for neuroprotection and tissue repair after an ischemic stroke. Additional studies in this indication are planned.

#### 3. Orthopedic diseases of the spine

#### Intervertebral disc repair

Subsequent to the reporting date of 31 December 2013. Mesoblast announced the 12-month results of its Phase 2 clinical trial in patients with chronic moderate to severe discogenic low back pain. When compared to the findings of the patients under placebo or control protocol at 12 months, MPC-treated patients had improvement in chronic lower back pain (reduction in mean pain score; increased proportion of patients achieving >50% reduction in pain score; increased proportion of patients achieving minimal residual back pain; reduced opioid use for pain relief; and reduced need for additional surgical and non-surgical interventions for persistent pain); improvement in function (reduction in mean disability score and increased proportion of patients achieving minimal residual functional disability); and improvement in radiographic features suggesting greater disc stability. MPC treatments also appeared to be well tolerated.

Based on the significantly greater market potential for use of non-surgical treatments in patients with degenerative disc disease, compared with surgical interventions such as spinal fusion, Mesoblast plans to commence a Phase 3 trial of non-invasive MPC injections to treat discogenic low back pain as its first area of focus for orthopedic spine disease.

#### Lumbar spinal fusion

Mesoblast reported in 2013 that a Phase 2 low back fusion clinical trial showed that implantation with MPCs was equivalent to standard of care hip autograft at 12 months post-surgery in terms of reducing pain and improving function, without the need for a second surgical procedure and its attendant morbidity risks. These positive results support progression to a Phase 3 trial.

The results were presented to the North American Spine Society 28th Annual Meeting in October 2013.

## 4. Oncology conditions associated with bone marrow transplantation

#### Acute Graft Versus Host Disease (GVHD)

Prochymal® is the world's first approved allogeneic stem cell therapeutic and the only stem cell therapeutic designated by the FDA as both an Orphan Drug and Fast Track product. Prochymal® is also available for treatments of acute GVHD in both children and adults in the United States under an expanded access program.

Conditional approvals for acute GVHD in children have been granted by Health Canada and MedSafe (New Zealand). Mesoblast is actively engaging regulatory authorities in the United States and Europe concerning moving the clinical development plan forward to fulfill requirements for marketing authorization pathways in this indication.

Additionally, Mesoblast intends to hold discussions with the FDA for the use of Prochymal® in adults with acute GVHD and liver or gut complications, based on the positive results in this patient sub-set generated in a Phase 3 trial.

The Company is reviewing the commercialization pathways for other markets as the ongoing use of Prochymal® through the United States expanded access program has significantly strengthened the clinical data package to support submissions for approvals in various jurisdictions.

In Japan, Mesoblast's partner JCR Pharmaceuticals has the exclusive rights to manufacture, develop and market the culture-expanded MSCs for GVHD in adult and children in Japan. JCR has stated that it intends to file for regulatory approval in Japan before 31 March 2014. If successful, it will be the first allogeneic cell- based product approved in Japan. Under its agreement with JCR, Mesoblast is entitled to milestone payments on product regulatory filing and approvals, royalties and other payments at pre-defined thresholds of cumulative net sales.

#### Cord blood expansion

The Phase 3 clinical trial using MPCs to expand hematopoietic precursors from cord blood for transplantation in cancer patients is ongoing. If this product is successful, it has the potential to increase the total number of unrelated donor transplants, and provide therapy for patients with malignant diseases for which transplantation is the only hope for a cure.

#### **Financial Summary**

#### Operating results

The net loss after tax for the half-year is \$30,859k (31 December 2012: \$27,785k), an increase in loss of \$3,074k (11%).

The increased loss was driven by an increase in expenses from continuing operations of \$9,104k, which has been offset by an increase in other income of \$6,854k, of which \$5,795k is attributable to research and development tax incentive revenue recorded in the current half-year.

The following sections provide more detail.

#### Revenue from continuing operations

	Dec 2013	Dec 2012	Movement
	\$'000	\$'000	\$'000
Development & commercialization revenue	8,215	9,894	(1,679)
Interest revenue	5,705	4,840	865
	13,920	14,734	(814)

This decrease in revenue from continuing operations of \$814k is due to a reduction of \$1,679k in commercialization revenue brought to account over the life of the partnered development programs upon the revision of estimated development timelines for those programs made in March 2013. Interest revenue increased by \$865k for the half-year, driven by the increase in cash on deposit from the capital raise of \$170m through the private placement of ordinary shares that occurred in March 2013. The impact of this increase has been offset by a reduction in interest rates available in the market place.

#### Other income

	Dec 2013 \$'000	Dec 2012 \$'000	Movement \$'000
Research & development tax incentive revenue	5,795	-	5,795
Foreign exchange gains	1,059	_	1,059
	6,854	_	6,854

The research and development tax incentive revenue reflects expected revenue to be received under the research and development tax incentive regime. The net foreign exchange gain has an equivalent net foreign exchange loss reported within management & administration expenses for the comparative period.

#### Expenses from continuing operations

Expenses from continuing operations reported for the current half-year were \$51,626k (31 December 2012: \$42,522k), a total increase of \$9,104k, the detail of which is as follows:

	Dec 2013 \$'000	Dec 2012 \$'000	Movement \$'000
Research & development	20,736	21,581	(845)
Manufacturing commercialization	13,212	9,141	4,071
Management & administration	17,678	11,800	5,878
	51,626	42,522	9,104
Equity settled share-based payment transactions (non-cash) included in the above items of expenditure	5,321	6,567	(1,246)
% of expenses from continuing operations	10.3%	15.4%	(5.1%points)

#### Research & development

Research & development (R&D) expenses total \$20,736k for the half year (31 December 2012: \$21,581k) resulting in a minimal decrease of \$845k (4%) from the comparative reported period. The R&D expenditure comprises of payments made to external service providers (eg contract research organisations (CROs)) for conducting preclinical and clinical trials, together with internal labour and support costs which are directly attributable to the programs.

During the current period 54% (HY2013: 34%) of the R&D expenditure noted above was incurred for our programs being developed for MPCs and MSCs to be delivered intravenously to treat inflammatory and immune-mediated diseases. The increase in expenditure compared to the previous period for these programs reflects the increased clinical trial activity across our Phase 2 trials for type 2 diabetes, end-stage kidney disease and rheumatoid arthritis during the current half year.

In support of the increasing level of research & development activities reported above, R&D staff numbers have grown from 43 (at 31 December 2012) to 60 (at 31 December 2013). The above reported R&D expenditure includes an amount of \$2,511k (31 December 2012: \$4,359k) for equity settled share-based payments, a non-cash expense item.

In line with the Group's policy and to comply with accounting standards, all costs associated with research & development, and manufacturing commercialization, are fully expensed in the period in which they are incurred as the Directors do not consider the Group can demonstrate all the factors required by accounting standards to be able to capitalize development expenditure at this time.

#### Manufacturing commercialization

Manufacturing commercialization expenditure totals \$13,212k for the half year (31 December 2012: \$9,141k) – an increase of \$4,071k (45%) over the comparative reported period. The manufacturing commercialisation expenditure comprises of mesenchymal lineage cell production for clinical trials, master cell bank production, and optimization of both the existing manufacturing processes and new bioprocessing technologies for commercial product yields and cost of goods reductions.

The increase in manufacturing commercialization expenditure for the current period is largely a result of increasing the clinical grade MPC supply to support our clinical trials over the next two to three years, including clinical grade production of 66% of the material needed to conduct the Phase 3 congestive heart failure trial. Cell production is being manufactured by one the of the world's leading biologics manufacturers, Lonza, in Singapore.

All manufacturing costs are expensed as incurred, there are no amounts carried within inventory on the balance sheet.

#### Management & administration

Management & administration expenses total \$17,678k for the half year (31 December 2012: \$11,800k) – an increase of \$5,878k (50%) over the comparative reported period. Management & administration expenditure includes business support costs including corporate finance activities, legal and professional fees, patent expenses, service department labour, and general office expenses. Note 2 to the financial statements provides further detail on expenditure.

The increase of \$5,878k for management & administration expenses is a result of the growth of our business as we embark on multiple Phase 3 programs and the costs that arise necessarily in support of that growth.

In particular, the following major areas of management & administration have reported increases of:

- \$1,696k (107%) for patent fees, legal fees, and other professional fees as a result of the acquisition of culture expanded mesenchymal stem cell assets and related patent portfolio from Osiris, together with international tax and legal advice to meet the needs of our globally expanding business;
- \$3,024k (47%) for labour and associated costs, of which \$413k relates to equity settled share-based payment transactions (a non-cash item), reflecting the growth of our business and internal resources;
- \$954k (29%) for general business overheads eg. rent, travel, and office expenses; and
- \$204k (85%) for commercialization & other one-off expenses, including a net decrease of \$813k in foreign exchange losses ^ over the previous half year.

^ The current reporting period reports a net foreign exchange gain of \$1,059k within other income, comprising a \$437k realized FX loss (2012: \$1,673k) and a \$1,496k unrealized FX gain (2012: \$860k).

Realized FX losses represent the cost of entering into forward contracts for our USD term deposits which are used to eliminate currency risk whilst we generate higher interest returns. These costs have fallen by \$951k due to a significantly higher level of forward contract cover in place in the previous period as a result of larger USD deposits held during the prior period.

Unrealized FX gains include marked to market revaluations of forward cover and translation of foreign currency supplier and intercompany loan balances at reporting date. The unrealized gains have increased by \$636k due to the fall in the AUD:USD exchange rate over the current period compared to a rising exchange rate in the comparative period.

#### Cash flows

Net cash outflows for the period were \$67,579k (31 December 2012: \$26,770k), an increase of \$40,809k, made up as follows:

	Dec 2013	Dec 2012	Movement
	\$'000	\$'000	\$'000
Cash outflows from operations	(48,027)	(24,999)	(23,028)
Cash outflows from investing activities	(21,209)	(3,402)	(17,807)
Cash inflows from financing activities	1,657	1,631	26
Net cash outflows – before FX on bank accounts	(67,579)	(26,770)	(40,809)

#### Operating cash flows

The operating cash out flows of \$48,027k (31 December 2012: \$24,999k) are made up of the following cash items:

- cash outflows of \$45,749k (31 December 2012: \$34,678k) for cash expenditure comprising of \$51,626k (31 December 2012: \$42,522k) of expenses from continuing operations as reported above, adjusted for non-cash expenses of \$5,877k (31 December 2012: \$7,844k), predominantly for equity settled share based payments and unrealized foreign exchange gains and losses, and changes in working capital of \$9,360k (31 December 2012: (\$856k));
- cash inflows of \$2,778k (31 December 2012: \$5,526k) from interest received; and
- cash inflows of \$4,304k (31 December 2012: \$3,297k) from tax refunds.

#### Investing cash flows

The investing cash out flows of \$21,209k (31 December 2012: \$3,402k) is mostly due to the one-off acquisition of Osiris' culture expanded mesenchymal stem cell therapeutic business (refer note 10 to the financial statements).

#### Financing cash flows

The cash inflows from financing activities of \$1,657k (31 December 2012: \$1,631k) relate to cash received for the exercise of options, and is at a consistent level with the prior period.

#### **Events Subsequent to Balance Date**

There have not been any events subsequent to the balance date, not otherwise disclosed in this report, which significantly affected or may significantly affect the operations of the Group, the results of its operations or the state of affairs of the company in subsequent financial periods.

#### Auditor's Independence Declaration

A copy of the auditor's declaration as required under Section 307C of the Corporations Act 2001 is included on page 8 of this report.

This report is made in accordance with a resolution of the directors.

#### **Rounding of Amounts**

The company is of a kind referred to in Class Order 98/100, issued by the Australian Securities and Investments Commission, relating to the 'rounding off' of amounts in the Directors' Report. Amounts in the Directors' Report have been rounded off in accordance with that Class Order to the nearest thousand dollars, or in certain cases to the nearest dollar.

Mr Brian Jamieson

Chairman

25 February 2014 Singapore



### **Auditor's Independence Declaration**

As lead auditor for the review of Mesoblast Limited for the half-year ended 31 December 2013, I declare that to the best of my knowledge and belief, there have been:

- a) no contraventions of the auditor independence requirements of the *Corporations Act* 2001 in relation to the review; and
- b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Mesoblast Limited and the entities it controlled during the period.

Dontage

Partner

PricewaterhouseCoopers

Melbourne 25 February 2014

## Income Statement for the half-year ended 31 December 2013

	Dec 2013	Dec 2012
Note	\$'000	\$'000
2(a)	13,920	14,734
2(b)	6,854	-
	20,774	14,734
	(20,736)	(21,581)
	(13,212)	(9,141)
	(17,678)	(11,800)
2(c)	(51,626)	(42,522)
	(30,852)	(27,788)
	(7)	3
	(30,859)	(27,785)
	Cents	Cents
	(9.72)	(9.69)
	(9.72)	(9.69)
	2(a) 2(b)	Note \$'000  2(a) 13,920  2(b) 6,854  20,774  (20,736) (13,212) (17,678)  2(c) (51,626)  (30,852) (7) (30,859)  Cents (9.72)

## Statement of Comprehensive Income for the half-year ended 31 December 2013

		Dec 2013	Dec 2012
	Note	\$'000	\$'000
Loss for the half-year		(30,859)	(27,785)
Items that may be reclassified to profit or loss			
Exchange differences on translation of foreign operations		13,739	(6,353)
Other comprehensive income/(loss) for the period, net of tax		13,739	(6,353)
Total comprehensive loss is attributable to the owners of Mesobla	ast Limited	(17,120)	(34,138)

## Statement of Changes in Equity for the half-year ended 31 December 2013

	Note	Issued Capital \$'000	Share Option Reserve \$'000	Foreign Currency Translation Reserve \$'000	Retained Earnings \$'000	Total \$'000
Balance at 1 July 2013		654,458	49,129	24,506	(97,827)	630,266
Loss for the half-year		-			(30,859)	(30,859)
Other comprehensive income		_	_	13,739	(00,000)	13,739
Total comprehensive profit/(loss) for the period		-	_	13,739	(30,859)	(17,120)
Transactions with owners in their capacity as owners:						
Contributions of equity net of						
transaction costs		19,289			_	19,289
		19,289	_	_	_	19,289
Transfer exercised options		1,736	(1,736)			-
Fair value of share-based payments		_	5,321	_	_	5,321
		1,736	3,585			5,321
Balance at 31 December 2013		675,483	52,714	38,245	(128,686)	637,756
Balance at 1 July 2012		485,004	37,505	(7,497)	(36,165)	478,847
Loss for the half-year		_	_		(27,785)	(27,785)
Other comprehensive loss		_	_	(6,353)	_	(6,353)
Total comprehensive loss for the period		-	-	(6,353)	(27,785)	(34,138)
Transactions with owners in their capacity as owners:						
Contributions of equity net of						
transaction costs		2,246	_	_	_	2,246
		2,246				2,246
Transfer exercised options		669	(669)	-	_	_
Fair value of share-based payments		_	6,567	_	_	6,567
		669	5,898		_	6,567
Balance at 31 December 2012		487,919	43,403	(13,850)	(63,950)	453,522

## Balance Sheet for the half-year ended 31 December 2013

	Note	Dec 2013 \$'000	Jun 2013 \$'000
Assets		<u> </u>	<del> </del>
Current Assets			
Cash & cash equivalents	3(a)	250,262	315,309
Trade & other receivables	4	16,855	12,063
Prepayments		1,073	986
Derivative financial instruments	5	3,350	3,486
Total Current Assets		271,540	331,844
Non-Current Assets			
Property, plant and equipment		3,150	2,757
Other non-current assets		2,125	1,277
Intangible assets	6	724,274	547,834
Total Non-Current Assets		729,549	551,868
Total Assets		1,001,089	883,712
Liabilities			
Current Liabilities			
Trade & other payables	7	30,903	21,308
Deferred revenue	· · · · · · · · · · · · · · · · · · ·	16,768	16,176
Provisions	8	11,932	13,104
Total Current Liabilities	<u> </u>	59,603	50,588
Non-Current Liabilities			
Provisions Provisions	8	233	203
Deferred revenue	U	50,302	56,617
Other payables	9	86,244	-
Deferred tax liability	0	166,951	146,038
Total Non-Current Liabilities		303,730	202,858
Total Liabilities		363,333	253,446
Net Assets		637,756	630,266
Equity			
Issued capital		675,483	654,458
Reserves		90,959	73,635
Accumulated losses		(128,686)	(97,827)
Total Equity		637,756	630,266

## Statement of Cash Flows for the half-year ended 31 December 2013

	Note	Dec 2013 \$'000	Dec 2012 \$'000
Cash Flows from Operating Activities			
Payments to suppliers and employees (inclusive of goods and service	es tax)	(55,109)	(33,822)
Interest received		2,778	5,526
Income taxes refunded		4,304	3,297
Net cash outflows in operating activities		(48,027)	(24,999)
Cash Flows from Investing Activities			
Payments for financial derivatives	3(c)	(319)	(1,332)
Payments for intellectual property and licences		(20,128)	
Payment for rental deposits		(770)	
Investment in fixed assets		(312)	(870)
Short term staff repayment/(advance)		320	(1,200)
Net cash outflows in investing activities		(21,209)	(3,402)
Cash Flows from Financing Activities			
Proceeds from issue of shares		1,678	1,631
Payments for share issue costs		(21)	_
Net cash inflows by financing activities		1,657	1,631
Net decrease in cash and cash equivalents		(67,579)	(26,770)
Cash and cash equivalents at beginning of year		315,309	206,749
FX gains/(losses) on the translation of foreign bank accounts		2,532	(1,328)
Cash and cash equivalents at end of year	3(a)	250,262	178,651

#### 1. Basis of Preparation of Half-Year Report

This condensed consolidated interim financial report for the half-year reporting period ended 31 December 2013 has been prepared in accordance with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Act 2001.

This condensed consolidated interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2013 and any public announcements made by Mesoblast Group during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

New standards that are applicable for the first time for the December 2013 half-year report are AASB 13 Fair Value Measurement, AASB 2012-2 Amendments to Australian Accounting Standards – Disclosures – Offsetting Financial Assets and Financial Liabilities and AASB 2012-5 Amendments to Australian Accounting Standards arising from Annual Improvements 2009-2011 Cycle. These standards have introduced new disclosures for the interim report but did not affect the entity's accounting policies or any of the amounts recognised in the financial statements.

#### 2. Revenue and Expenses from Continuing Operations

(a) Revenue from continuing operations	Dec 2013	Dec 2012
	\$'000	\$'000
Commercialization revenue	8,215	9,894
Interest revenue	5,705	4,840
	13,920	14,734
(b) Other Income		
Research & development tax incentive	5,795	
Foreign exchange gains	1,059	
	6,854	-
(c) Expenses from continuing operations		
Clinical trial research & development	9,466	10,081
Manufacturing production & development	11,706	8,100
Employee benefits		
Salaries and employee benefits	13,550	9,085
Defined contribution superannuation expenses	196	156
Equity settled share-based payment transactions ^	5,321	6,567
Total employee benefits	19,067	15,808
Depreciation and amortization of non-current assets		
Plant and equipment depreciation	454	282
Intellectual property amortization	54	51
Total depreciation and amortization of non-current assets	508	333
Other expenses		
Overheads & administration	4,724	3,107
Consultancy	2,631	2,452
Legal, patent and other professional fees	2,475	1,433
Intellectual property expenses (excluding the amount amortized above)	1,049	395
Foreign exchange losses	_	813
Total other expenses	10,879	8,200
Toal expenses from continuing operations	51,626	42,522

<sup>^</sup> Equity settled share-based payment transactions have been reflected in the Income Statement functional expense categories as follows: research & development \$2,511k (2012: \$4,359k), manufacturing commercialization \$414k (2012: \$225k) and management & administration \$2,396k (2012: \$1,983k).

#### 3. Cash and Cash Equivalents

	Dec 2013	Jun 2013
3(a) Cash Balances	\$'000	\$'000
Cash at bank	11,849	12,744
Deposits at call ^	238,413	302,565
	250,262	315,309

<sup>^</sup> The terms and conditions of the deposits allow the Group to withdraw funds on demand.

#### 3(b) Term Deposits Held

		Dec 2013			Jun 2013	
AUD	Interest Rate	Interest Rate	AUD	Interest Rate	Interest Rate	AUD
	– Low	– High	\$'000	– Low	– High	\$'000
Funds invested			238,413			302,565
Interest earned for the period	od 3.45%	4.50%	5,522	3.85%	4.66%	9,776

The Group's policy is to invest its cash in A-1+ short-term rated (or better) institutions and products.

#### 3(c) Foreign Currency Risk Management

The Group has certain clinical, regulatory and manufacturing activities which are being conducted internationally. The primary currency exposure of the Group are the clinical trial activities which are occurring offshore in the United States of America and Singapore. As a result of these activities, the Group has certain amounts owing which are denominated in US dollars (USD) and Singapore dollars (SGD). These foreign currency balances give rise to a currency risk, which is the risk of the exchange rate moving, in either direction, and the impact it may have on the Group's financial performance.

The Group manages its currency risk by ensuring it holds appropriate levels of foreign currencies to fund its foreign operations and activities for a period of time. The foreign currency holdings are accumulated over time. Due consideration is given to the trend of the currencies to the Australian Dollar (AUD) and market conditions at the time the currency is purchased.

#### Forward contracts

The Group has entered into these forward contracts to take advantage of increased interest rate yields available when investing AUD on deposit. The Group sells USD and buys AUD from the bank at a pre-agreed FX rate and agrees to sell the AUD value and buy USD from the bank on maturity also at a pre-agreed rate. As these FX rates are known at the outset there is no currency risk. During the life of the forward contract, the AUD held is invested in AUD term deposits. Therefore, of the \$319k (2012: \$1,332k) noted in the statement of cashflows as payments for financial derivatives, interest revenue of \$450k (2012: \$1,861k) was received, resulting in a net cash gain of \$130k (2012: \$529k). The effective interest rate earned on the various deposits, after allowing for the cost of the forward contracts, was between 0.9% and 1.4% during the half-year period (2012: 1.2% and 1.8%).

It should be noted that trading in speculative derivatives is strictly prohibited in accordance with the Group's treasury and financial risk management policy.

#### 4. Trade and Other Receivables

	Dec 2013	Jun 2013
	\$'000	\$'000
Interest receivable	6,233	3,306
Sundry debtors	505	8
Income tax and tax incentives recoverable	9,896	8,316
Other recoverable taxes (GST & VAT)	221	113
Loan to an employee covered by a contract	_	320
	16,855	12,063

All trade and other receivable balances are within their due dates and none are considered to be impaired at 31 December 2013 and 30 June 2013.

#### 5. Fair Value Measurement of Financial Instruments

#### (a) Fair value hierarchy

The following table presents the Group's financial assets and financial liabilities measured and recognised at fair value at 31 December 2013 and 30 June 2013 on a recurring basis, categorised by level according to the significance of the inputs used in making the measurements:

	Quoted prices			
	in active markets	Significant other	Significant	
f	or identical assets	observable	unobservable	
	or liabilities	inputs	inputs	Fair Value
	Level 1	Level 2	Level 3	Total
At 31 December 2013	\$'000	\$'000	\$'000	\$'000
Assets				
Financial assets at fair value through prof	it or loss			
Derivative financial instruments	-	3,350	-	3,350
Total Assets	_	3,350	_	3,350
Liabilities				
Contingent consideration payable (note	9) –	-	86,244	86,244
Total Liabilities	_		86,244	86,244
	Level 1	Level 2	Level 3	Total
At 30 June 2013	\$'000	\$'000	\$'000	\$'000
Assets				
Financial assets at fair value through prof	iit or loss			
Derivative financial instruments	-	3,486	-	3,486
Total Assets	_	3,486	_	3,486
Liabilities				
Contingent consideration payable (note	9) –	-	-	_
Total Liabilities	_	_	_	_

The Group did not measure any financial assets or financial liabilities at fair value on a non-recurring basis as at 31 December 2013.

#### (b) Valuation techniques used to derive level 2 fair values

The Group used the following techniques to determine the fair value measurements categorised in Level 2:

<sup>-</sup> The fair value of forward foreign exchange contracts is determined using forward exchange rates at the balance sheet date.

#### (c) Fair value measurements using significant unobservable inputs (level 3)

The following table presents the changes in level 3 instruments for the half year ended 31 December 2013:

	Contingent	
	consideration payable	Total
	\$'000	\$'000
Opening balance 30 June 2013		_
Initial recognition (note 10(a))	81,660	81,660
Exchange difference	4,584	4,584
Closing balance 31 December 2013	86,244	86,244

#### (i) Transfers between levels 2 and 3 and changes in valuation technique

There were no transfers between the levels of the fair value hierarchy in the six months to 31 December 2013. There were also no changes made to any of the valuation techniques applied as of 30 June 2013.

#### (ii) Valuation inputs and relationship to fair value

The following table summarises the quantitative information about the significant unobservable inputs used in level 3 fair value measurements:

Description	Fair value at 31 December 2013 \$'000	Valuation technique	Unobservable inputs*	Range of inputs (weighted average)	Relationship of unobservable inputs to fair value
Contingent consideration payable	86,244	Discounted cash flows	Risk adjusted discount rate	11% – 13% (12.5%)	A change in the discount rate by 0.5% would increase/decrease the fair value by 2%.
			Expected unit revenues	n/a	A 10% increase in the price assumptions adopted would increase the fair value by 5%.

<sup>\*</sup> There were no significant inter-relationships between unobservable inputs that materially affect fair values.

#### (iii) Valuation processes

An independent valuation of the contingent consideration, as at 11 October 2013 (acquisition date), was carried out by Deloitte Touche Tohmatsu.

The Audit and Risk Committee and valuation team have reviewed this valuation as at 31 December 2013, and determined there has been no change to the fair value. A key reason for this determination is that the independent valuation was completed recently and no significant events have occurred since it was completed that would lead to the valuation changing.

### 6. Intangible Assets

		Acquired licenses to	In-process research & development	
	Goodwill	patents	acquired	Total
	\$'000	\$'000	\$'000	\$'000
At 1 July 2012				
Cost	116,211	1,621	379,747	497,579
Accumulated amortization	_	(360)	_	(360)
Accumulated impairment	_	_	_	_
Net book amount	116,211	1,261	379,747	497,219
Year ended 30 June 2013				
Opening net book value	116,211	1,261	379,747	497,219
Additions	_	_	1,614^	1,614
Exchange differences	11,476	123	37,504	49,103
Amortization charge	_	(102)	_	(102)
Impairment charge	_	_	-	_
Closing net book value	127,687	1,282	418,865	547,834
At 1 July 2013				
Cost	127,687	1,748	418,865	548,300
Accumulated amortization	-	(466)	=	(466)
Accumulated impairment	=	-	_	-
Net book amount	127,687	1,282	418,865	547,834
Half-year ended 31 December 2013				
Opening net book value	127,687	1,282	418,865	547,834
Additions	14,748	963	132,485 ^	148,196
Exchange differences	5,495	58	22,745	28,298
Amortization charge	_	(54)	-	(54)
Impairment charge	=	-	_	-
Closing net book value	147,930	2,249	574,095	724,274
At 31 December 2013				
Cost	147,930	2,772	574,095	724,797
Accumulated amortization	_	(523)	-	(523)
Accumulated impairment	_	_	_	_
Net book amount	147,930	2,249	574,095	724,274

<sup>^</sup> The total additions of In-process research & development recorded in Business Combination note 10 is \$134,099k. This amount is the total of the Additions in both the year ended 30 June 2013 and half-year ended 31 December 2013.

#### 7. Trade and Other Payables

	Dec 2013	Jun 2013
	\$'000	\$'000
Trade payables	13,885	20,780
Purchase consideration (note 10(a))	16,486	
Employee benefits	532	528
	30,903	21,308

#### 8. Provisions

Dec 2013	Jun 2013
\$'000	\$'000
9,605	9,266
2,327	3,838
11,932	13,104
233	203
233	203
	9,605 2,327 11,932

#### (a) Movements

Movements in each class of provision during the financial year, other than employee benefits, are set out below:

	10tal \$'000_
Carrying amount at start of period – 1 July 2013	9,266
Foreign exchange difference	339
Additional provision recognized (charged to profit/loss)	<u> </u>
Carrying amount at end of period – 31 December 2013	9,605

#### (b) Provisions other

During the ordinary course of business the Group occasionally has disputes with suppliers and other third parties. This provision allows for those disputes in the event the disputed amounts become due and payable. Further disclosure is considered to be prejudicial to the Group.

#### 9. Other Payables

	Dec 2013	Jun 2013
	\$'000	\$'000
Contingent consideration (note 5(c))	86,244	-
	86,244	-

#### 10. Business Combinations

#### (a) Summary of acquisition

On 11 October 2013, the Group acquired the culture-expanded mesenchymal stem cell (ceMSC) business of Osiris Therapeutics Inc.

The acquisition is complementary in its nature with many commercial and strategic benefits. The potential benefits derived from acquiring the approved and late-phase ceMSC products include:

- near term market launch of a mesenchymal lineage product in major jurisdictions;
- broadened late-phase clinical programs in strategic areas of focus;
- leveraged roll out of infrastructure, skills and expertise needed to commercialize Mesenchymal Precursor Cell (MPC) products;
- ownership of extensive long-term clinical data from over 1,500 patients treated with cultured MSC's, including safety,
   efficacy and repeat dosing data; and
- acquisition of new intellectual property which is highly complementary to Mesoblast's existing patent estate.

Details of the purchase consideration, the net assets acquired and goodwill are as follows:

#### Purchase consideration at fair value

	Fair Value at
	Acquisition Date
	AUD '000
Cash on closing	21,196
Cash payment due on the six month anniversary of the agreement (Fair Value) ^	15,610
Securities allotment [2,948,729 shares were allotted] ^ ^	15,873
Contingent consideration ^ ^ (note 10(b))	81,660
Total purchase consideration	134,339

#### Net assets acquired at fair value

	Fair Value at Acquisition Date	
	AUD '000	
Property, plant and equipment	240	
Intangible assets: (in-process research & development)	134,099	
Deferred tax liability on future revenue streams, recorded in accordance with AASB 3	(14,748)	
Net identifiable assets acquired	119,591	
add: Goodwill	14,748	
Net assets acquired	134,339	

The fair value amounts reported above are preliminary.

All assets acquired and purchase consideration amounts are denominated in USD. The amounts presented above are in AUD and have been translated at the rate applicable at the acquisition date (11 October 2013) being 1AUD:0.9450USD. The goodwill is attributable to the deferred tax liability that is required to be recognised on the difference between the intangible asset's book value compared to its tax value.

No amount of goodwill is expected to be deducted for tax purposes.

- ^The cash payment due on the six month anniversary of the agreement of \$15,610k has a USD demoninated value of USD15,000k. This amount has been translated at the 31 December 2013 exchange rate of 1:0.8948 and is recorded in trade & other payables at an amount of AU\$16,486k (refer note 7).
- ^ MSB securities were issued as consideration upon the transfer of assets on 18 December 2013, which had a value of \$16,717k on that date.
- ^ ^ Contingent consideration of \$81,660k reported above has a USD denominated value of USD77,169k. This amount has been translated at the 31 December 2013 exchange rate of 1:0.8948 and recorded in non-current other payables at an amount of AU\$86,244k (refer note 9).

#### (b) Contingent consideration

In the event that certain pre-determined milestones and royalties are achieved additional consideration is payable. The fair value of the contingent consideration is set out in the table below. The fair value estimates have been calculated on the basis of fair value less cost to sell by using the income approach, with reference to both the excess earnings and relief from royalty methods as set out below:

	Fair Value at	
	Acquisition Date	
The fair value of contingent consideration	AUD '000	
Fair value of cash or stock payable, dependent on achievement of future		
late-stage clinical or regulatory targets (i)	24,507	
Fair value of royalty payments from commercialization of the intellectual		
property acquired (ii)	57,153	
	81,660	

- i. The contingent consideration payable for each milestone is a fixed dollar amount and can be paid either in cash or through the allotment of Mesoblast Ltd securities (ASX: MSB) at the date of payment, at the discretion of the Mesoblast Group. The potential undiscounted amount of the contingent consideration for milestones is a minimum of USDNil and a maximum of USD50m.
- ii. The amount of the contingent consideration payable as royalties is variable. The contingent consideration paid could range from zero dollars if no sale of product occurs, up to a maximum that is unlimited. This maximum is calculated at a commercial arm's length percentage of net sales. Royalty payments will cease after a 10 year commercial sales period. Royalties are payable in cash after the conclusion of the period in which the sales were made.

#### (c) Purchase consideration - cash outflow

	31 December 2013 AUD '000
Cash consideration (fair value) owed pursuant to the asset purchase agreement	36,806
less: amount paid during the full year ended 30 June 2013	(1,537)
less: balance owing six months after acquisition date (fair value)	(15,610)
Cash outflow reported for the current reporting period ^	19,659

<sup>^</sup>included within cashflows from investing activities within the statement of cashflows.

There were no acquisitions in the half-year ending 31 December 2012.

#### (d) Revenue and profit contribution

The business was fully integrated in the Group's existing operations at acquisition date, and, as such, distinct financial information is not recorded. The Group estimates the assets acquired contributed revenue of \$Nil and a net loss of approximately \$1,240k to the Group for the period from 11 October 2013 to 31 December 2013. On that basis, it is expected that, the Group would have reported consolidated revenue from continuing operations of \$Nil and consolidated net loss of \$2,782k for the half-year ended 31 December 2013 if the business combination had occurred on 1 July 2013.

#### (e) Acquisition-related costs

Directly attributable acquisition-related costs of approximately \$334k are included in management and administration expenses in the income statement, and in the operating cash flows section in the statement of cash flows, for the half-year ended 31 December 2013.

#### 11. Equity Securities Issued

	Dec 2013 Shares	Dec 2012 Shares	Dec 2013 \$'000	Dec 2012 \$'000
Issues of ordinary shares during the half-year				
Consideration for acquired licenses to patents	70,164	_	418	_
Consideration for In-process research & development acquired	2,948,729	_	16,717	_
Placement of shares under LFSP ^	1,165,000	825,000	_	-
Exercise of share options ^ ^	851,000	1,180,216	2,154	2,246
	5,034,893	2,005,216	19,289	2,246

<sup>^</sup> Shares are issued to employees and consultants in accordance with the Mesoblast Australian Loan Funded Share Plan (LFSP).

#### 12. Events Occurring after the Reporting Date

There are no events that have arisen after 31 December 2013 and prior to the signing of this financial report that would likely have a material impact on the financial results presented.

<sup>^</sup> Options have been issued to employees, directors and consultants in accordance with the Mesoblast Employee Share Option Plan (ESOP). The shares issued and share capital received on the exercise of options are recorded above.

## Directors' Declaration

In accordance with a resolution of directors of Mesoblast Group,

In the opinion of the directors:

- (a) the financial statements and notes set out on pages 9 to 22 are in accordance with the Corporations Act 2001, including:
  - (i) complying with Accounting Standards, the *Corporations Regulations 2001* and other mandatory professional reporting requirements, and
  - (ii) giving a true and fair view of the consolidated entity's financial position as at 31 December 2013 and of its performance for the half year ended on that date, and
- (b) there are reasonable grounds to believe that Mesoblast Group will be able to pay its debts as and when they become due and payable

This declaration is made in accordance with a resolution of the directors.

Mr Brian Jamieson

Chairman

25 February 2014 Singapore



# Independent auditor's review report to the members of Mesoblast Limited

#### Report on the Half – Year Financial Report

We have reviewed the accompanying half-year financial report of Mesoblast Limited (the company), which comprises the balance sheet as at 31 December 2013, the income statement, statement of comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, selected explanatory notes and the directors' declaration for Mesoblast Limited group (the consolidated entity). The consolidated entity comprises the company and the entities it controlled during that half-year.

#### Directors' responsibility for the half-year financial report

The directors of the company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Australian Auditing Standard on Review Engagements ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the financial report is not in accordance with the Corporations Act 2001 including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2013 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001. As the auditor of Mesoblast Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.



#### Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Mesoblast Limited is not in accordance with the *Corporations Act 2001* including:

- a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2013 and of its performance for the half-year ended on that date; and
- b) complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001.

Tricewaterhouse Coopers

John Teoman

Partner |

Melbourne 25 February 2014