



Half-Year Report 31 December 2012

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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 2012. In order to comply with the provisions of the *Corporations Act 2001*, the Directors report the following information:

## Directors

The following persons were Directors of Mesoblast Group during the whole of the half-year and up to the date of this report (unless specified):

Name	Position
Mr Brian Jamieson	Chairman
Professor Silviu Itescu	Executive Director
Mr Donal O'Dwyer	Non-executive Director; Chair of the Nomination and Remuneration Committee
Mr Michael Spooner	Non-executive Director; Chair of the Audit and Risk Committee
Mr Ben-Zion Weiner	Non-executive Director

## Review of Operations

Mesoblast's strategic advantages as a global leader in the field of regenerative medicine are based on the quality of its Mesenchymal Precursor Cell (MPC) technology, the breadth of the platform, the robustness of its patent protection, and the company's financial strength which enables sufficient resource allocation for realistic prospects of simultaneous product commercialization.

Consequently, the increase in expenditures in the current half-year period relative to the same period in the prior year are consistent with the overall corporate strategy and reflect the significant increase in effort the Company has put, principally, behind its clinical and manufacturing operations.

During the half-year period from 1 July 2012 through to 31 December 2012 Mesoblast has made substantial progress in achieving important milestones in strengthening its intellectual property portfolio, its product clinical development and its manufacturing processes.

### Strengthened Intellectual Property

Intellectual property is the lifeblood of any innovative biotechnology company. Mesoblast has a robust intellectual property (IP) portfolio that provides exclusive rights in our key markets to a series of patent families covering compositions, methods of manufacture, and uses of MPCs for product commercialization.

Mesoblast had a new patent granted by the United States Patent and Trade Mark Office (USPTO) which confers on the company exclusive rights through to March 2029 to compositions-of-matter covering its current products. This patent extends by more than seven years Mesoblast's exclusive commercial rights in the United States, the world's largest healthcare market, to MPC compositions-of-matter beyond those rights already conferred by earlier patents whose expiry had previously been extended to November 2021.

Two additional new patents were granted which provide Mesoblast with exclusive MPC product commercial rights and protection through to 2025 in China. These patents provide Mesoblast with long-term composition-of-matter protection for the Company's MPC products derived from an unlimited range of tissue sources including bone marrow, adipose tissue, placenta, umbilical cord, and dental pulp. These Chinese patents underpin Mesoblast's corporate strategy to target the world's largest emerging market for regenerative medicines, and to protect its manufacturing processes and know-how.

### Progress in Manufacturing

Our manufacturing strategy aims to ensure that we have top tier manufacturing capabilities, process development skills, and geographically diversified facilities. Our strategy for innovative manufacturing research and development is to facilitate product delineation through changes in formulation or dosages, biologic modifications of cells, development of products sourced from different tissues, and combining cells with different modes of delivery or devices.

Our partnership with world leading biologics manufacturer, Lonza, support's Mesoblast's overall manufacturing objectives, and importantly derisks supply capabilities. In order to ensure uninterrupted product supply we utilize facilities across multiple jurisdictions, including the United States and exclusive access to Lonza's Singapore operations for allogeneic cell manufacturing.

During the period, we have focused our efforts on optimizing product manufacturing to meet regulatory Phase 3 trial requirements, scaling up the existing manufacturing process to ensure product supply for our increasing clinical trial needs, and optimizing next generation technology to ensure long-term cost-of-goods reductions and production yields in accordance with anticipated commercial rollout forecasts.

In the reporting period, Mesoblast established with the FDA a clear pathway for commercial manufacturing supply of our cell therapy products, including agreement on the manufacturing process to supply MPC products for Phase 3 clinical trials. The FDA agreed that Mesoblast's extensive characterization and testing of its MPC technology platform was acceptable and consistent with manufacturing expectations for Phase 3 clinical supplies and with the proposed assays to demonstrate potency for MPC products, a key requirement for entry into Phase 3 clinical trials.

#### **Progress in Clinical Development**

The ability to develop an industrially scaled up allogeneic cell product which has low costs-of-goods, is relatively homogeneous with batch to batch consistency, and has reproducible release criteria, means that we can focus on clinical indications that have large unmet medical needs and where our technology may offer paradigm-changing benefits. Based on these criteria, and positive results from preclinical animal studies, we have chosen to focus on three large areas of clinical need: (a) systemic diseases of excessive inflammation and immunity which can be addressed by intravenous administration of our MPC products, (b) degenerative diseases of the spine where our MPC products can be locally administered to generate new bone and repair intervertebral discs, and (c) cardiovascular diseases where our MPC products can be locally administered to improve heart function.

#### **Products Delivered Intravenously for Diseases of Inflammation and Immunity**

Mesoblast is developing products to treat prevalent systemic disorders caused by excessive inflammation and immune-mediated mechanisms. These disorders include inflammatory diseases of the joints such as rheumatoid arthritis, type 2 diabetes and its complications, particularly diabetic kidney disease; and inflammatory lung diseases, such as asthma and pulmonary fibrosis.

The rationale for targeting these disorders is that they are all associated with excessive activation of multiple immune pathways, and Mesoblast's MPCs have been shown in preclinical studies to have a broad immunomodulatory mechanism of action (MOA), simultaneously inhibiting multiple pathways of inflammation and immune activation, including T cells and monocytes. Consequently, we believe that the broad immunomodulatory effects of our MPCs could provide tangible benefits to patients with debilitating autoimmune diseases.

#### **Rheumatoid Arthritis**

Rheumatoid Arthritis (RA) is an autoimmune disease caused by aberrant activation of multiple immune pathways, ultimately resulting in joint destruction. Existing biologic treatments target only single immune pathways, resulting in incomplete responses, need for chronic administration, and potentially unacceptable infectious adverse events. The broader effects of Mesoblast's MPCs on multiple immune pathways suggest that they may be particularly useful agents for reducing the inflammation and permanent joint damage associated with progression of RA. Indeed, in a sheep 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.

In January 2013, Mesoblast received clearance from the United States Food and Drug Administration (FDA) to begin a Phase 2 trial of our proprietary allogeneic, or 'off-the-shelf', MPCs in patients with active RA. The trial will be a randomized, double-blind placebo-controlled dose escalation study to evaluate the safety, tolerability 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. This Phase 2 trial in RA is the first in a series of programs designed to establish the credentials of our intravenous product formulation for a broad-based spectrum of inflammatory and immunologic conditions.

### **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 blood glucose control and on changes in various inflammatory markers, including C-reactive protein (C-RP).

The objective of this trial is to identify an optimal dose for both glucose control and for reduction in parameters of inflammation, as was seen in prior studies in diabetic non-human primates following intravenous injection of a single dose of allogeneic MPCs. Additionally, 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.

End-stage kidney disease has a high rate of annual progression to dialysis, and is the major predictor of cardiovascular death in diabetic patients, independently of blood sugar, lipids, and blood pressure. Mortality risk is amplified in diabetics with high circulating levels of C-RP.

Mesoblast is planning 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. Based on our earlier observation of reduced C-RP levels in diabetic non-human primates following MPC therapy, an important additional objective of treatment in these patients will be to assess whether MPC therapy may have a cardioprotective effect.

### **Products Delivered by Local Administration**

#### **Orthopedic Spine Diseases**

Our orthopedic product pipeline is targeting the fastest growing market in orthopedics, treatment of spine diseases. During the period, we have completed and reported results of a Phase 2 trial of our bone repair product for use in conjunction with spinal fusion surgery, and have completed recruitment of a Phase 2 trial of our intervertebral disc regeneration product.

### **Spine Fusion Surgery for Advanced Disc Degeneration**

For patients whose intervertebral discs have degenerated too extensively to contemplate repair, bony fusion of adjacent vertebra is the primary option to eliminate chronic and debilitating pain. There is a major unmet need for new technologies to achieve fusion that are safe, effective, and that eliminate the need for bone autograft.

In January, we released Phase 2 clinical trial results of Mesoblast's NeoFuse® product comprising allogeneic MPCs used in lumbar spinal fusion surgery. In the 24-patient multi-center trial in the United States, 8 patients per group were randomized to one of three arms, bone autograft standard of care (Control), 25 million MPCs (25M), and 75 million MPCs (75M). Patients underwent the surgical procedure, one or two level fusions using a posterior approach to the spine, and were evaluated for safety and efficacy.

MPCs were well tolerated with no cell-related serious adverse events and no ectopic bone formation at all. Notably, 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, fusion was achieved in 85.7% of patients in the 25M treatment group compared to 62.5% in the 75M and 75% in the control patient groups. Overall, patients from all three treatment groups had a clinically significant and comparable decrease in low back and leg pain, assessed on the Visual Analogue Scale, and in functional improvement, assessed by the Oswestry Disability Index questionnaire.

The results showed that 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.

#### **Restoration of early disc damage**

Mesoblast is also developing a non-surgical adult stem cell treatment for restoration of early disc degeneration in order to reduce lower back pain and improve function. Non-surgical restoration of early disc damage represents a much larger market opportunity than surgical fusion, with no existing alternative therapies available for this clearly defined unmet medical need. Mesoblast's double-blind, placebo-controlled Phase 2 clinical trial has completed enrollment of 100 patients with intervertebral disc disease. While the 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.

#### **Cardiovascular Diseases**

Mesoblast has an important strategic partnership with Teva Pharmaceutical Industries Ltd which is focussed on the development of innovative products for major cardiovascular and neurologic diseases. Teva provides Mesoblast with Phase 3 trial expertise, proven capability to obtain product regulatory approvals, and global distribution strength. The lead product in this alliance 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 hospitalization events for decompensated heart failure or 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.

#### **Outlook**

In the second half of the financial year, we expect to continue to report on clinical outcomes from a number of Phase 2 programs and to initiate new programs in line with the overall corporate strategy. We will continue to evaluate the appropriate strategy for each therapeutic indication, balancing risk, investment and potential value creation, including additional potential strategic partnerships.

## Financial Results

### Operating results

The net loss before tax for the half-year is \$27.8m (31 December 2011: \$17.6m), an increase in loss of \$10.2m.

The increased loss was driven by a reduction in revenue from continuing operations and other income of \$4.3m and an increase in expenses from continuing operations of \$5.9m as detailed below.

### Revenue from continuing operations

Revenue from continuing operations reported for the Group during the current period is \$14.7m (31 December 2011: \$18.6m), a decrease of \$3.9m. Of this, interest revenue increased by \$0.1m, whilst commercialization revenue decreased for the period by \$4.0m. This decrease reflects an extension of the period over which the upfront payment of USD130m is being amortized. This payment was received by the Company upon entering into the development and commercialization agreement with Cephalon, Inc. (now Teva Pharmaceutical Industries Ltd) during the financial year ended 30 June 2011. This payment is being recognized as revenue over the life of the development program in accordance with Australian Accounting Standards.

### Expenses from continuing operations

Expenses from continuing operations reported for the current period is \$42.5m (31 December 2011: \$36.6m), a total increase of \$5.9m. Expenses by major operational category, with share-based payments expense reported separately, are as follows:

	Half-year 2012 \$m	Half-year 2011 \$m	Movement \$m
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)
	<b>35.9</b>	<b>32.0</b>	<b>3.9</b>
Share-based payments expense	6.6	4.6	2.0
<b>Total expenses from continuing operations</b>	<b>42.5</b>	<b>36.6</b>	<b>5.9</b>

### Research and development

Research & development expenses have increased by \$4.5m over the corresponding period as a result of the Group's increased investment in clinical, regulatory and new product development. The increased spend was as expected given the broadening strategy for clinical development, and specifically reflects completion of the 100 patient recruitment for the disc repair phase 2 trial, the initiation and start of recruitment for the diabetes phase 2 trial, new preclinical initiatives to broaden the intravenous programs in inflammation and immunity, and greater regulatory activity for new clinical trials anticipated to commence in 2013.

In line with the Group's policy and to comply with accounting standards, all costs associated with research and development 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 expenses have risen by \$1.0m this half-year compared to last half-year as a result of our investment into the following manufacturing activities:

- optimization of product manufacturing to meet regulatory Phase 3 trial requirements;
- scaling up the existing manufacturing process to ensure product supply for our increasing clinical trial needs; and
- optimizing our next generation technology to ensure long-term cost-of-goods reductions and improved production yields in accordance with anticipated commercial rollout forecasts.

### Management and Administration

Management and administration expenses have decreased by \$1.6m this half-year compared to last half-year as a reflection of the Company's focus to achieve cost reductions through efficiencies in our supportive and administrative processes.

**Share-based payment expense**

Share-based payment expenses have increased by \$2.0m reflecting the annual issue of options and loan funded shares issued pursuant to the Company's employee share plans, which requires the issues to be valued (using Black Scholes valuation model) and expensed over the vesting period in accordance with Australia Accounting Standards.

**Cash flows**

Net cash outflows for the period were \$26.8m (31 December 2011: \$29.1m), a reduction of \$2.3m, made up as follows:

	Half-year 2012 \$m	Half-year 2011 \$m	Movement \$m
Cash flows from operations – (outflow)/inflow	(30.5)	(36.9)	6.4
Cash flows from investing activities – (outflow)/ inflow	2.1	4.7	(2.6)
Cash flows from financing activities – (outflow)/ inflow	1.6	3.1	(1.5)
Net cash flows (outflow)/inflow – before FX	(26.8)	(29.1)	2.3

**Operating cash flows**

The decrease in cash outflows from operations reflects the net movement in tax payments of \$10.4m, comprising of a prepayment of tax of \$7.1m in half-year 2011 and a refund of \$3.3m in half-year 2012. With this taken into account, payments to suppliers for clinical and manufacturing activities have risen by \$4.0m in line with our increased research and development activities.

**Investing cash flows**

The decrease in cash inflows from investing activities is due to a short-term advance (\$1.2m), further investment in fixed assets (\$0.5m) to support our clinical programs and a reduction in net interest (after forward contracts) of (\$0.9m).

**Financing cash flows**

The decrease in cash inflows from financing activities was due to a reduction in the volume and value of share options exercised.

**Balance Sheet**

The Group has cash reserves as at 31 December 2012 of \$178.6m (30 June 2012: \$206.7m). These cash reserves remain sufficient to complete current clinical programs and manufacturing activities.

**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 7 of this report.

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

**Mr Brian Jamieson**  
Chairman

8 February 2013  
Melbourne





## Auditor's Independence Declaration

As lead auditor for the review of Mesoblast Limited for the half year ended 31 December 2012, 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.

A handwritten signature in black ink, appearing to read 'John Yeoman', with a long horizontal flourish extending to the right.

John Yeoman  
Partner  
PricewaterhouseCoopers

Melbourne  
8 February 2013

## Consolidated Income Statement for the half-year ended 31 December 2012

	Note	Half-year 2012 \$	Half-year 2011 \$
<b>Revenue from continuing operations</b>	2(a)	14,734,138	18,639,003
Other income		–	328,006
		14,734,138	18,967,009
<b>Expenses from continuing operations</b>			
Research and development		(21,581,283)	(14,923,239)
Manufacturing commercialization		(9,140,751)	(7,914,470)
Management and administration		(11,800,270)	(13,743,232)
	2(b)	(42,522,304)	(36,580,941)
<b>Loss before income tax</b>		<b>(27,788,166)</b>	<b>(17,613,932)</b>
Income tax benefit/(expense)		3,005	(26,513,031)
<b>Loss for the period attributable to the owners of Mesoblast Limited</b>		<b>(27,785,161)</b>	<b>(44,126,963)</b>
<b>Losses per share from continuing operations attributable to the ordinary equity holders of the Group:</b>			
		<b>Cents</b>	<b>Cents</b>
Basic – losses per share		(9.69)	(15.52)
Diluted – losses per share		(9.69)	(15.52)

*The above consolidated income statement should be read in conjunction with the accompanying notes.*

## Consolidated Statement of Comprehensive Income for the half-year ended 31 December 2012

	Note	Half-year 2012 \$	Half-year 2011 \$
<b>Loss for the period</b>		<b>(27,785,161)</b>	<b>(44,126,963)</b>
<b>Other comprehensive income</b>			
Exchange differences on translation of foreign operations		(6,353,397)	15,302,474
<b>Other comprehensive (loss)/profit for the period, net of tax</b>		<b>(6,353,397)</b>	<b>15,302,474</b>
<b>Total comprehensive loss for the period attributable to the owners of Mesoblast Ltd</b>		<b>(34,138,558)</b>	<b>(28,824,489)</b>

*The above consolidated statement of comprehensive income should be read in conjunction with the accompanying notes.*

## Consolidated Statement of Changes in Equity for the half-year ended 31 December 2012

	Attributable to owners of Mesoblast Group					Total \$
	Note	Issued Capital \$	Share Option Reserve \$	Foreign Currency Translation Reserve \$	Retained Earnings \$	
<b>Balance at 1 July 2011</b>		477,114,981	25,664,152	(21,915,730)	34,980,770	515,844,173
Loss for the half-year as reported in the 2012 half-year financial statements		–	–	–	(44,126,963)	(44,126,963)
Other comprehensive income		–	502,352	14,800,122	–	15,302,474
<b>Total comprehensive profit/(loss) for the half-year</b>		–	502,352	14,800,122	(44,126,963)	(28,824,489)
<b>Transactions with owners in their capacity as owners:</b>						
Contributions of equity net of transaction costs		3,104,519	–	–	–	3,104,519
		3,104,519	–	–	–	3,104,519
Tax effect of options deductible for tax		–	1,336,325	–	–	1,336,325
Transfer exercised options		1,373,907	(1,373,907)	–	–	–
Fair value of share-based payments		–	4,565,391	–	–	4,565,391
		1,373,907	4,527,809	–	–	5,901,716
<b>Balance at 31 December 2011</b>		481,593,407	30,694,313	(7,115,608)	(9,146,193)	496,025,919
<b>Balance at 1 July 2012</b>		485,004,166	37,504,679	(7,496,518)	(36,164,544)	478,847,783
Loss for the year		–	–	–	(27,785,161)	(27,785,161)
Other comprehensive loss		–	–	(6,353,397)	–	(6,353,397)
<b>Total comprehensive loss for the half-year</b>		–	–	(6,353,397)	(27,785,161)	(34,138,558)
<b>Transactions with owners in their capacity as owners:</b>						
Contributions of equity net of transaction costs		2,245,987	–	–	–	2,245,987
		2,245,987	–	–	–	2,245,987
Tax effect of options deductible for tax		–	–	–	–	–
Transfer exercised options		668,654	(668,654)	–	–	–
Fair value of share-based payments		–	6,566,776	–	–	6,566,776
		668,654	5,898,122	–	–	6,566,776
<b>Balance at 31 December 2012</b>		487,918,807	43,402,801	(13,849,915)	(63,949,705)	453,521,988

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

## Consolidated Balance Sheet for the half-year ended 31 December 2012

	Note	31 December 2012 \$	30 June 2012 \$
<b>Assets</b>			
<b>Current Assets</b>			
Cash and cash equivalents	3	178,650,939	206,748,798
Trade and other receivables		7,408,867	10,668,742
Prepayments		322,705	318,580
<b>Total Current Assets</b>		<b>186,382,511</b>	<b>217,736,120</b>
<b>Non-current Assets</b>			
Property, plant and equipment		2,651,156	1,998,430
Deferred tax asset		3,437,535	3,502,429
Intangible assets	4	487,941,952	497,218,571
<b>Total Non-current assets</b>		<b>494,030,643</b>	<b>502,719,430</b>
<b>Total Assets</b>		<b>680,413,154</b>	<b>720,455,550</b>
<b>Liabilities</b>			
<b>Current Liabilities</b>			
Trade and other payables		13,216,629	11,969,147
Deferred revenue		18,270,888	28,209,500
Derivative financial instruments		731,236	1,406,762
Provisions	5	1,690,461	2,908,900
<b>Total Current Liabilities</b>		<b>33,909,214</b>	<b>44,494,309</b>
<b>Non-current Liabilities</b>			
Deferred revenue		54,812,664	56,361,109
Deferred tax liability		130,441,063	132,911,392
Provisions	5	7,728,225	7,840,957
<b>Total Non-Current Liabilities</b>		<b>192,981,952</b>	<b>197,113,458</b>
<b>Total Liabilities</b>		<b>226,891,166</b>	<b>241,607,767</b>
<b>Net Assets</b>		<b>453,521,988</b>	<b>478,847,783</b>
<b>Equity</b>			
Issued capital		487,918,807	485,004,166
Reserves		29,552,886	30,008,161
Retained earnings/(accumulated losses)		(63,949,705)	(36,164,544)
<b>Total Equity</b>		<b>453,521,988</b>	<b>478,847,783</b>

The above consolidated balance sheet should be read in conjunction with the accompanying notes.

## Consolidated Statement of Cash Flows for the half-year ended 31 December 2012

	Note	Half-year 2012 \$	Half-year 2011 \$
<b>Cash Flows from Operating Activities</b>			
Payments to suppliers and employees (inclusive of goods and services tax)		(30,524,851)	(37,019,668)
Government grants and other income received		–	125,311
<b>Net cash inflows/(outflows) in operating activities</b>		<b>(30,524,851)</b>	<b>(36,894,357)</b>
<b>Cash Flows from Investing Activities</b>			
Interest received		5,526,022	5,039,657
Forward contract payments	3(c)	(1,332,250)	–
Investment in fixed assets		(869,578)	(361,203)
Short term staff advance		(1,200,000)	–
<b>Net cash inflows/(outflows) in investing activities</b>		<b>2,124,194</b>	<b>4,678,454</b>
<b>Cash Flows from Financing Activities</b>			
Proceeds from issue of shares		1,631,203	3,104,519
<b>Net cash inflows by financing activities</b>		<b>1,631,203</b>	<b>3,104,519</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>(26,769,454)</b>	<b>(29,111,384)</b>
Cash and cash equivalents at beginning of year		206,748,798	263,227,585
FX gains/(losses) on the translation of foreign bank accounts		(1,328,405)	6,726,497
<b>Cash and cash equivalents at end of year</b>	<b>3(a)</b>	<b>178,650,939</b>	<b>240,842,698</b>

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

## Notes to the Consolidated Financial Statements for the half-year ended 31 December 2012

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

This condensed consolidated interim financial report for the half-year reporting period ended 31 December 2012 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 2012 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.

#### *Revision of Accounting Estimates*

##### Revenue Recognition

The Group received a total upfront cash payment of USD130m during the financial year ended 2011 upon the signing of a development and commercialization agreement for certain products. This payment is being recognized as revenue over the development period of the products. The development period is assessed every six months, and revenue recognition rates adjusted accordingly. During the current period, the Group has revised the development life estimate and adjusted the revenue accordingly. Refer to note 2 for the effect of the change in estimate.

### 2. Revenue and Expenses from Continuing Operations

2(a) Revenue from continuing operations	Half-year 2012 \$	Half-year 2011 \$
Commercialization revenue	9,893,652	13,943,990
Interest revenue	4,840,486	4,695,013
	14,734,138	18,639,003

#### 2(b) Expenses from continuing operations

Expenses from continuing operations contains a share-based payments expense of \$6.6m (2011: \$4.6m). This share-based payments expense is reflected in research and development \$4.4m (2011: \$2.2m), manufacturing commercialization \$0.2m (2011: nil) and management and administration \$2.0m (2011: \$2.4m).

## Notes to the Consolidated Financial Statements for the half-year ended 31 December 2012

### 3. Cash and Cash Equivalents

3(a) Cash Balances	31 December 2012 \$	30 June 2012 \$
Cash at bank ^	13,123,306	2,537,528
Deposit at call	417,530	879,216
Term deposits (3b)	165,110,103	203,332,054
	178,650,939	206,748,798

^ Of this balance, USD 1,180,431 (AUD 1,158,239) is not available for use. These funds are held in an account named Mesoblast Inc. at the Bank of America according to the terms of an Irrevocable Standby Letter of Credit which is security for the sublease agreement for our occupancy of 505 Fifth Avenue, New York, New York, United States of America. The Letter of Credit is security for the full and faithful performance and observance by the subtenant of the terms, covenants and conditions of the sublease. The Letter of Credit is deemed to automatically extend without amendment for a period of one year at each anniversary but it will not automatically extend beyond the final expiration of 31 July 2021.

### 3(b) Term Deposits Held

31 December 2012				30 June 2012		
AUD	Interest Rate – Low	Interest Rate – High	AUD	Interest Rate – Low	Interest Rate – High	AUD
Funds invested			161,450,628			200,353,445
Interest earned for the period	4.25%	5.20%	4,829,329	5.10%	6.00%	10,105,469
USD				USD		
Funds invested			3,800,000			3,035,500
Interest earned for the period	0.50%	0.53%	4,247	0.70%	0.70%	363,248

The Group's policy is to invest its cash in AA- 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 to the Group is the clinical trial activities which are occurring offshore on behalf of the parent (an Australian company) in the United States of America and manufacturing activities occurring in 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 the currency risk by evaluating the trend of the relevant foreign currency rates (FX rates) to the Australian dollar and making decisions as to the levels to hold in each currency by assessing its future activities which will likely be incurred in those currencies.

#### *Forward contracts*

The Group has entered 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 \$1.3m noted in the statement of cashflows as forward contract payments, interest revenue of \$1.8m was received, resulting in a net cash gain of \$0.5m. The effective interest rate earned on the various deposits, after allowing for the cost of the forward contracts, was between 1.2% and 1.8% during the half-year period (2011: nil).

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



## Notes to the Consolidated Financial Statements for the half-year ended 31 December 2012

### 4. Intangible Assets

	Goodwill \$	Patents, Trademarks and other \$	Intellectual Property \$	Total \$
<b>At 1 July 2011</b>				
Cost	109,738,837	690,000	365,192,550	475,621,387
Accumulated amortization	–	(295,187)	–	(295,187)
Net book value	109,738,837	394,813	365,192,550	475,326,200
<b>Year ended 30 June 2012</b>				
Opening net book value	109,738,837	394,813	365,192,550	475,326,200
Additions	–	924,823	–	924,823
Adjustment for final value on acquisition of subsidiary company	2,142,907	–	–	2,142,907
Exchange differences	4,329,219	5,774	14,554,285	18,889,278
Amortization charge	–	(64,367)	–	(64,637)
Closing net book value	116,210,963	1,260,773	379,746,835	497,218,571
<b>At 30 June 2012</b>				
Cost	116,210,963	1,620,404	379,746,835	497,578,202
Accumulated amortization	–	(359,631)	–	(359,631)
Net book value	116,210,963	1,260,773	379,746,835	497,218,571
<b>Half-year ended 31 December 2012</b>				
Opening net book value	116,210,963	1,260,773	379,746,835	497,218,571
Exchange differences	(2,159,930)	(7,910)	(7,058,084)	(9,225,924)
Amortization charge	–	(50,695)	–	(50,695)
Closing net book value	114,051,033	1,202,168	372,688,751	487,941,952
<b>At 31 December 2012</b>				
Cost	114,051,033	1,612,224	372,688,751	488,352,008
Accumulated amortization	–	(410,056)	–	(410,056)
Net book amount	114,051,033	1,202,168	372,688,751	487,941,952

## Notes to the Consolidated Financial Statements for the half-year ended 31 December 2012

### 5. Provisions

	31 December 2012	30 June 2012
	\$	\$
<b>Current</b>		
Provision for short term incentive	1,450,461	2,908,900
Provision other ^	240,000	–
	1,690,461	2,908,900
<b>Non-current</b>		
Provision for long service leave	174,047	143,717
Provisions other ^	7,554,178	7,697,240
	7,728,225	7,840,957

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

### 6. Events Occurring after the Reporting 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.

# 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 8 to 16 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 2012 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

8 February 2013  
Melbourne



## 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, which comprises the balance sheet as at 31 December 2012, and the income statement, the 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 the Mesoblast Limited Group (the consolidated entity). The consolidated entity comprises both Mesoblast Limited (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 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 2012 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*.

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*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 2012 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*.

A handwritten signature in cursive script that reads 'PricewaterhouseCoopers'.

PricewaterhouseCoopers

A handwritten signature in cursive script that reads 'John Yeoman'.

John Yeoman  
Partner

Melbourne  
8 February 2013