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Mesoblast Reports Half-Year 2013 Financial Results
Provides Strategic Update on Key Areas of Product Development

Melbourne, Australia; 11 February 2013 – Mesoblast Limited (ASX:MSB; OTC ADR:MBLTY) today provided its half-year 2013 financial results, as well as a strategic update on the key areas of product development for its Mesenchymal Precursor Cell (MPC) platform technology, particularly in the fields of inflammation and immunity.

Mesoblast Chief Executive Professor Silviu Itescu said: “Our strong cash position enables us to pursue our key areas of MPC product development in parallel in order to most efficiently bring our products to market, either on our own or with strategic distribution partners.”

The Company reported strong cash reserves of $178.6 million for the 2013 financial half-year reporting period ended 31 December 2012.

Cash-flow from operating activities for the current period includes a tax refund of $3.3 million, reflecting an appropriate cash burn for operations (net of tax) of $33.8 million for the half-year. In comparison to the previous corresponding period, expenses from operations (excluding share-based payments) were up $3.9 million to $35.9 million. Research & development expenses have increased by $4.5m to $17.2 million and manufacturing expenditures by $1 million to $8.9 million. Management and administration costs have decreased by $1.6 million to $9.8 million. Revenue from continuing operations for the half-year were $14.7 million, down $3.9 million from the last corresponding period principally due to an extension of the period over which the USD130 million upfront payment received in December 2010 is being amortized. There was a net loss before tax of $27.8 million for the half-year, compared with $17.6 million for the previous corresponding period.

Professor Itescu added: "The increase in expenditures during the last half-year reflected the Group’s greater investment in clinical and regulatory activities, manufacturing, and new product development. The increased spend was in line with expectations given our broadening strategy for clinical development of our intravenous product for immunomodulation as we gain greater understanding of the broad mechanisms of action (MOA) of our unique MPCs.

"Specifically, during the period we initiated new Phase 2 clinical programs of our intravenous product for diseases of inflammation and immunity, including diabetes and rheumatoid arthritis, completed recruitment in the 100-patient Phase 2 trial for disc repair, initiated new preclinical studies in inflammatory lung diseases, and increased product manufacturing as necessary to support these programs,” he said.

Key Areas Targeted for Mesoblast's MPC Product Development

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

I. systemic diseases of excessive inflammation and immunity which can be addressed by intravenous administration of our MPCs.
II. orthopedic diseases of the spine where our MPCs can be locally administered to generate new bone and repair intervertebral discs.
III. cardiovascular diseases where our MPC products can be locally administered to improve heart function.

I. Products Delivered Intravenously for Diseases of Inflammation and Immunity

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

Rheumatoid Arthritis

- In January 2013 Mesoblast received clearance from United States Food and Drug Administration (FDA) to begin Phase 2 trial of proprietary allogeneic, or "off-the-shelf MPCs in patients with active Rheumatoid Arthritis (RA).
- Trial will be 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.
- In an animal model of RA, MPC treatment significantly decreased the T cell and monocyte derived inflammatory cytokines TNF-alpha, IL-6 and IL-17 in the diseased joint and reduced tissue pathology.
- MOA provides the rationale for strategic development of MPCs in RA both in patients with incomplete responses to biologic inhibitors of the TNF-alpha pathway alone and as a first-line biologic treatment in those not responding to conventional anti-rheumatic agents.
- In addition, a second Phase 2 trial of MPCs as a first-line biologic treatment for active RA is planned to commence in Europe in 1H 2013.

Type 2 Diabetes and Diabetic Kidney Disease

- Type 2 diabetes is a disease of chronic inflammation which results in insulin resistance in fat tissues and vascular complications in various organs, including the kidneys, heart and eyes.
- Mesoblast is in the midst of a Phase 2 clinical trial in 60 patients with early type 2 diabetes not adequately maintained on oral glucose-reducing agents. The patients are being evaluated over 12 weeks for effectiveness of a single intravenous MPC dose on changes in various inflammatory markers, including C-reactive protein (C-RP), and on blood glucose control.
- We expect that this multi-center trial will set the foundation for evaluating MPCs in the treatment of patients with more advanced diabetes in order to target the life-threatening complications of the disease, such as renal failure and cardiovascular disease.
- Mesoblast plans to initiate a Phase 2 trial in the second half of FY 2013 to evaluate whether a single intravenous MPC injection can stabilize or reverse end-stage kidney disease in diabetics.

II. Products Delivered Locally for Orthopedic Diseases of the Spine

Spine Fusion Surgery for Advanced Intervertebral 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 which are safe, effective, and that eliminate the need for bone autograft.
- In January 2013, Phase 2 clinical trial results of Mesoblast's NeoFuse® product, comprising allogeneic MPCs used in lumbar spinal fusion surgery, were released.
- 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.
- 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, patients from all three treatment groups had similar rates of fusion success and all three 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.

Non-Surgical Restoration of Early Intervertebral Disc Disease

- 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.

III. Products Delivered Locally for Cardiovascular Diseases

- Mesoblast has an important strategic partnership with Teva Pharmaceutical Industries Ltd which focuses 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 leading 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.

Mesoblast Limited
Mesoblast Limited is a world leader in the development of biologic products for the broad field of regenerative medicine. Mesoblast's patented Mesenchymal Precursor Cell technology is being developed for an extensive range of major clinical diseases, including inflammatory and immunologic conditions of the joints and lungs, diabetes and its complications, orthopedic spine conditions, and cardiovascular disorders.

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