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mesoblast
the regenerative medicine company

MESOBLAST REPORTS STRONG HALF-YEAR FINANCIAL RESULTS

New York, USA, 25 February and Melbourne, Australia; 26 February 2014: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC:MBLTY) today provided its 2014 half-year financial results and operational highlights.

Over the reporting period, progression of the Company's Mesenchymal Precursor Cell (MPC) clinical trial programs and strategic acquisition of culture-expanded Mesenchymal Stem Cell (MSC) assets positions Mesoblast potentially by the end of this year with late-stage products in all four of its core therapeutic areas:

1. Intravenously-delivered products for systemic inflammatory and immune-mediated diseases

2. 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

Mesoblast Chief Executive Silviu Itescu said "Mesoblast's acquisition of late-stage MSC assets provides opportunity for earlier product launch and revenues, while our strong cash balance allows us to bring multiple MPC products within our pipeline to market."

2014 Half-Year Highlights

- Strong cash reserves of $250.3 million at 31 December 2013.

- 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.

- 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, resulting in broadening of market opportunities with additional Phase 3 programs, accelerated commercial product launch, and strengthening of leadership position in regenerative medicine.

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- Mesoblast collaborator, JCR Pharmaceuticals, announced plans to submit for registration in Japan use of 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.

Total cash outflows reported for the current period was $67.6 million, which includes cash outflows of $20.1 million for the acquisition of culture-expanded MSC assets and other intellectual property assets. In comparison to the six months ended 31 December 2012, the net loss after tax increased by $3.0 million (11%) to $30.8 million.

Revenue from continuing operations and other income for the half-year increased by $6.0m to $20.8 million, primarily due to research & development tax incentive income of $5.8 million recorded in the current half-year.

Expenses from continuing operations increased by $9.1 million to $51.6 million, principally due to the Mesoblast Group's greater investment in clinical and regulatory activities, manufacturing, and key personnel. A key component was production of clinical grade MPCs for the Phase 3 trial in congestive heart failure which has now commenced. The Group continues to invest in people who bring industry and development expertise as it transitions to a company executing multiple late-stage programs.

About Mesoblast

Mesoblast Limited (ASX:MSB; USOTC:MBLTY) is a world leader in the development of biologic products for the broad field of regenerative medicine. The Company's proprietary technologies include its highly purified, immunoselected Stro-1/Stro-3 positive Mesenchymal Precursor Cells (MPCs), culture-expanded Mesenchymal Stem Cells (MSCs), Dental Pulp Stem Cells (DPSCs), and expanded Hematopoietic Stem Cells (HSCs). Mesoblast's protein technologies are based on factors derived from its proprietary cellular platforms, including Stromal Derived Factor-1 (SDF-1). Mesoblast's allogeneic or 'off-the-shelf' regenerative medicine products are being developed for the treatment of conditions with significant unmet medical needs. Product development focus is in four major and distinct areas - systemic diseases with an underlying inflammatory and immunologic etiology; cardiac and vascular diseases; orthopedic diseases of the spine; and improving outcomes of bone marrow transplantation associated with oncology or genetic conditions. www.mesoblast.com

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