asx announcement

mesoblast
the regenerative medicine company

MESOBLAST 2015 HALF-YEAR RESULTS

New York, USA, and Melbourne, Australia; 12 February 2015: Mesoblast Limited (ASX: MSB, USOTC: MBLTY) today provided its 2015 half-year financial results and operational highlights. Mesoblast held cash reserves of $149.2 million at 31 December 2014.

During the reporting period, Mesoblast continued to leverage its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells (MLCs), to establish what the Company believes to be the most advanced regenerative medicine product portfolio in the industry.

Mesoblast has five product candidates that are in active Phase 3 trials or are Phase 3-ready and is well positioned to have the first industrially manufactured allogeneic stem cell products approved in Japan and the United States.

Half-Year Operational Highlights

Product candidate MPC-150-IM for congestive heart failure (CHF):

- Phase 3 trial in patients with CHF is recruiting well across multiple North American sites.
- Phase 3 trial is enriched for patients with advanced heart failure, based on inclusion criteria of high NT-proBNP levels and a heart failure-related hospitalization within the past nine months.
- Patients with advanced heart failure continue to have the greatest unmet need due to highest risk of heart failure-related major adverse cardiac events (HF-MACE) and are expected to be the optimal target for MPC-150-IM therapy.
- Agreement with National Institutes of Health (NIH) on the conduct of a 120-patient trial using MPC-150-IM in patients with advanced or end-stage CHF requiring mechanical circulatory support.

Product candidate MPC-06-ID for chronic discogenic low back pain (CDLBP):

- Phase 3 clinical program for CDLBP has been initiated.
- 12-month results of Phase 2 CDLBP trial presented at North American Spine Society Annual Meeting showing a single injection of MPC-06-ID resulted in sustained improvement and function compared with controls.
- Key patent granted through 2029 in the United States covering Mesoblast's product candidates for the treatment of degenerated intervertebral discs.

Product candidates MSC-100-IV and JR-031 for acute graft versus host disease (aGVHD):

- Phase 3 trial of MSC-100-IV for the treatment of steroid-refractory aGVHD in children has been initiated.
- JCR has filed for Japanese regulatory approval for JR-031 in aGVHD.

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Product candidate MPC-300-IV for immune-mediated diseases:

- Phase 2 trial evaluating each of two doses against placebo in patients with biologic-refractory rheumatoid arthritis is ongoing.
- First dose cohort has completed recruitment, six months follow-up, and continues to be evaluated. Second dose cohort continues to actively enroll.
- Phase 2 trial evaluating each of two doses against placebo in patients with diabetic kidney disease has completed recruitment, six months of follow-up, and continues patient evaluation.

Scaleable manufacturing:

- Mesoblast has made substantial advances in the development of 3-D manufacturing processes with greater capacity to improve efficiency and yields, with potential to result in lower costs-of-goods.
- Proprietary serum-free media has been developed, and has the potential to greatly enhance the yields achieved in manufacturing of product candidates and eliminate source material constraints.

Half-Year Financial Results Highlights

- Mesoblast held cash reserves of $149.2 million at 31 December 2014.
- Total revenue from continuing operations and other income was $25.9 million, an increase of $5.1 million on the previous corresponding half-year period, primarily due to foreign exchange gains and a milestone payment received from Japanese partner, JCR Pharmaceuticals Co. Ltd (JCR), on its submission of JR-031 for marketing approval to the Japanese Regulatory Authority.
- Net operating cash outflow was $56.5 million, compared with outflows of $48.0 million during the previous corresponding half-year period, driven primarily by increased spend on our Tier 1 and Tier 2 clinical programs.
- The Company reported a net loss of $50.8 million, principally due to an increase of $10.8 million in cash expenditure related to progress in our clinical programs, and a $10.7 million increase in contingent consideration pertaining to the acquisition of culture-expanded MSC assets.
- The contingent consideration above is a non-cash item which will predominantly be payable on successful achievement of product commercialization, and royalties payable will be funded from the profits generated.

Mesoblast Limited
Mesoblast Limited (ASX: MSB; USOTC: MBLTY) is a global leader in regenerative medicine. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells (MLCs), to establish a broad portfolio of late stage product candidates. Mesoblast's allogeneic or 'off-the-shelf' cell product candidates target significantly advanced stages of diseases where there are highly unmet medical needs, including cardiovascular conditions, orthopedic disorders, immunologic/inflammatory disorders and oncology/hematology conditions. Lead product candidates under investigation include MPC-150-IM for chronic congestive heart failure, in partnership with Teva Pharmaceutical Industries Ltd., MPC-06-ID for chronic discogenic low back pain, MSC-100-IV for acute graft versus host disease, and MPC-300-IV for biologic refractory rheumatoid arthritis and diabetic nephropathy.

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