asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS 2015 FINANCIAL YEAR RESULTS AND PROVIDES UPDATE ON PHASE 3 CHRONIC HEART FAILURE PROGRAM

New York, USA, and Melbourne, Australia; 17 August 2015: Mesoblast Limited (ASX: MSB; USOTC: MBLTY) today reported its 2015 full financial year results, and provided an update on important changes to its Phase 3 chronic heart failure program.

At 30 June 2015, the Company had cash reserves of $144.1 million compared with $196.4 million at the end of the previous financial year.

Chief Executive Silviu Itescu said: "We have made strong progress during the past year in moving forward our Phase 3, Tier 1 clinical programs, and have appropriately focused our resources on their execution.

"In addition, during the year our portfolio targeting inflammatory diseases has emerged with the potential to be a major new opportunity.

"We are particularly pleased with the outcome of the recent meeting between our development and commercialization partner Teva Pharmaceutical Industries Ltd (Teva) and the United States Food and Drug Administration (FDA) regarding our Phase 3 chronic heart failure program. The ongoing Phase 3 trial continues to recruit well and, as a result of the FDA meeting, has the potential for early completion based on overwhelming efficacy."

Update On Important Changes To The Phase 3 Chronic Heart Failure Program

Following the meeting between Teva and the FDA, important changes to the Phase 3 chronic heart failure program for MPC-150-IM have been agreed.

Key outcomes of the FDA meeting were as follows:

There will be a reduction in the total number of subjects to be recruited for the ongoing Phase 3 trial, using a time to first event analysis of heart failure-related major adverse cardiovascular events (HF-MACE) as the primary endpoint, from approximately 1,730 to 1,165.

An interim analysis will be performed in the ongoing Phase 3 trial when 50% of the HF-MACE have occurred, which will include a test for superiority allowing for the possibility of stopping of the trial early based on overwhelming efficacy.

A second, confirmatory study is planned to be conducted in parallel in an identical patient population of approximately 500 subjects using recurrent HF-MACE as the primary endpoint.

The use of recurrent HF-MACE as a primary endpoint in the confirmatory study is supported by a new analysis of the completed Phase 2 trial, where patients treated with MPC-150-IM had no HF-MACE over 36 months of follow-up, compared with 11 recurrent HF-MACE in the control group ($p<0.001$, log rank test). This analysis will be presented in full at an upcoming cardiovascular scientific meeting.

The clinical data from these two studies will be supportive to each other for product approval.

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Chronic Discogenic Low Back Pain (CDLBP) Program

The Phase 3 program in CDLBP is recruiting well across North American sites. We have received positive feedback from discussions with the European Medicines Agency and expect to expand the program to European sites.

Acute Graft Versus Host Disease (GVHD) Program

Our Japanese partner JCR Pharmaceuticals Co. Ltd. filed in September 2014 for Japanese approval for acute GVHD in children and adults.

Through a meeting with the FDA, we have identified a pathway to accelerated USA approval for our pediatric GVHD product candidate. An open-label Phase 3 study of approximately 60 children is actively recruiting in the USA.

Emerging Inflammatory Portfolio Has Potential To Be A Major New Opportunity

MPC-300-IV has been elevated to our Tier 1 product portfolio based on positive clinical results obtained in patients with diabetic kidney disease which were presented at the late-breaking scientific sessions of the 75th American Diabetes Association 2015 annual meeting.

The results of the Phase 2 trial in diabetic kidney disease demonstrated that a single infusion of MPC-300-IV resulted in preservation or improvement in renal function over at least 24 weeks, relative to controls. In addition, the results indicated an anti-inflammatory mechanism of action and identified biomarkers predictive of treatment response. Clinical trial design planning is underway for a Phase 2b/3 study.

The first cohort of a 48-patient Phase 2 trial for patients with biologic refractory rheumatoid arthritis has completed enrollment, with the second cohort actively recruiting across multiple sites in the United States.

Significant Progress In Manufacturing To Support Tier 1 Products

Substantial advances have been made in development of consistent high yield manufacturing processes to improve efficiency and yields in large commercial-grade bioreactors. Furthermore, an in-house proprietary serum-free media has been identified, and is being developed to deliver step-change yield improvements.

Full Year FY15 Finance Highlights

Our loss after tax for the year was $119.4 million compared with $81.0 million for the prior period. The increased loss was a result of expenses from continuing operations increasing by $43.8 million from $118.1 million to $161.9 million. Of the $43.8 million increase, expenses from continuing operations have increased by $33.2m (28%) in constant currency as we continue to invest in our late-stage pipeline. The remaining $10.6 million increase results from the depreciating AUD:USD exchange rate.

The Company had cash reserves of $144.1 million at 30 June 2015. Net cash consumption in the current period of $52.2 million was half that of FY14 ($118.9 million).

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, 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. The lead therapeutic product candidates under investigation include MPC-150-IM for chronic heart failure, MPC-06-ID for chronic discogenic low back pain, MSC-100-IV for acute graft versus host disease, and MPC-300-IV for diabetic nephropathy and biologic refractory rheumatoid arthritis.

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