asx announcement

mesoblast
the regenerative medicine company

MESOBLAST UNVEILS PATH TO BRING ITS KEY PRODUCTS TO MARKET

New York, USA, and Melbourne, Australia; 26 August 2014: Regenerative medicine company Mesoblast Limited (ASX: MSB; USOTC: MBLTY) today reported 2014 financial results and unveiled its strategy to prioritize and bring to market clinically differentiated products based on its proprietary Mesenchymal Precursor or Stem Cell (MPC or MSC) technologies.

The Company has created a product-focused organizational structure and will preferentially allocate resources to those products with the greatest mid-term revenue potential.

2014 Financial Year Highlights

- Cash reserves of $196.4 million at 30 June 2014
- Net loss after tax increased by $19.3 million (31.3%) to $81.0 million as a result of increased investment in clinical development, commercial manufacturing and investment in employees
- Normalized cash burn for 2014 was $78.2 million compared with $61.9 for 2013
- In addition, total cash outflows included an investment of $35.6 million for the acquisition of the culture-expanded Mesenchymal Stem Cell assets of Osiris Therapeutics Inc.

Corporate Strategy

The corporate strategy incorporates five imperatives:

1. Create clinically differentiated products
2. Focus on bringing late-stage products to market and portfolio prioritization
3. Enable manufacturing scale-up to meet demands of the portfolio
4. Leverage expanding talent base to continue to establish a culture of shared leadership and accountability
5. Continue to build strategic partnerships.

In anticipation of mid-term product revenues, Mesoblast has built an experienced, product focused team for late-phase clinical execution and market launch.

Mesoblast has a portfolio of cell-based regenerative medicine products, with five in Phase 3 or Phase 3-ready. The portfolio has been organized into Tier 1, Tier 2, and pipeline products based on specific criteria.

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Tier 1 products have mid-term revenue potential, and include:

1. MSC-100-IV for steroid-refractory Graft Versus Host Disease (GVHD)
- Mesoblast partner JCR Pharmaceuticals plans to file for registration for GVHD in children and adults in Japan in H2 2014
- Mesoblast plans a product registration filing for pediatric GVHD in 2016, with a United States launch in 2017.

2. MPC-06-ID for Chronic Discogenic Lower Back Pain (CDLBP)
- Positive End of Phase 2 meeting with the United States Food and Drug Administration supports progression into Phase 3 with the composite endpoint that was met in Phase 2
- Phase 3 trial to be initiated before the end of 2014.

3. MPC-150-IM for congestive heart failure
- This product is being developed with our commercial and development partner Teva Pharmaceutical industries (Teva) for New York Heart Association (NYHA) class II-III heart failure patients
- The National Institutes of Health (NIH) is conducting a 120-patient study in advanced/NYHA class IV patients

Tier 2 products are in Phase 2 or 3, have committed funding through to the next value inflection point, and will advance into Tier 1 on merit of data, market opportunity or partnering capability. These include:

- MSC-100-IV: Intravenous administration of MSCs for Crohn's disease
- MPC-300-IV: Intravenous administration of MPCs for systemic inflammatory and immune-mediated conditions including diabetic kidney disease and rheumatoid arthritis.
- MPC-25-IC: Intra-coronary delivery of MPCs for acute myocardial infarction
- MPC-25-Osteo: Surgical use of MPCs for surgical lumbar fusion
- MPC-CBE: Expansion of hematopoietic stem cells for bone marrow transplantation

Pipeline: These products are in early clinical or preclinical development, and include MPCs for neurological diseases, lung diseases, knee osteoarthritis, and vascular or retinal conditions of the eye (e.g. age-related macular degeneration)

Commercial Scale Manufacturing - Objectives:
1. Distinct manufacturing processes for each product
2. Commercial scale processes with batch-to-batch consistencies and reproducible release criteria
3. Ensure commercial product supply is aligned with projected market needs; production hub in Singapore, scale-up in 3D bioreactors, optimized cost-of-goods

Outlook for the Next 12 Months

Mesoblast expects to execute on the following objectives in the next 12 months:

MSC-100-IV for GVHD
- Pediatric trial recruitment to support product registration filing for accelerated approval in US
- Parallel US trial in adults with liver/gut GVHD
- Commercial manufacturing to support product launches
- JCR partner to file for registration in Japan

MPC-06-ID for CDLBP
- Commence and actively recruit Phase 3 program in North America

MPC-150-IM for CHF
- Continue recruiting Phase 3 trial in NYHA class II/III heart failure across North American sites
- Interim analysis for safety/surrogate efficacy endpoints for heart failure-related Major Adverse Cardiac Events
- Recruitment of NIH-funded trial in advanced/NYHA class IV heart failure
- Commercial manufacturing to support product launches

Tier 2 products/pipeline
- Decision points for type 2 diabetes/diabetic kidney disease, Crohn's Disease and rheumatoid arthritis.

Strategic alliances
- Focus on strategic partnerships and other funding sources to enhance commercial success

Mesoblast Limited
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 adult stem cell 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' cell-based products are targeting substantial market areas of unmet medical need, including cardiac and metabolic diseases, inflammatory/immune-mediated conditions, oncology, and orthopedic diseases. Lead products are MSC-100-IV for steroid refractory acute Graft Versus Host Disease, MPC-06-ID for chronic discogenic lower back pain and MPC-150-IM for congestive heart failure. www.mesoblast.com

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