## asx announcement



# MESOBLAST ACQUIRES OSIRIS' CULTURE EXPANDED STEM CELL THERAPEUTIC BUSINESS

Firms Mesoblast's Leadership Position in Regenerative Medicine Broadens Market Opportunities with New Phase 3 Programs Accelerates Commercial Product Launch

> Mesoblast to Host Conference Call on 10 October 7.30PM EDT (US)/ 11 October 10.30AM AEDT (AU) Webcast link - http://www.brrmedia.com/event/116950/

**Melbourne**, **Australia**; **11 October 2013**: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC:MBLTY) today announced the acquisition of the entire culture-expanded mesenchymal stem cell (MSC) business of Osiris Therapeutics (NASDAQ:OSIR) by the Mesoblast Group.

"The many commercial and strategic benefits of this transaction firm Mesoblast's leadership position in the global regenerative medicine industry," said Mesoblast Chief Executive Officer Professor Silviu Itescu.

The benefits derived from acquiring the approved and late-phase MSC products include:

- near term market launch of a mesenchymal lineage product in major jurisdictions;
- broadened late-phase clinical programs in strategic areas of focus; and
- leveraged roll out of infrastructure, skills and expertise needed to commercialize Mesenchymal Precursor Cell (MPC) products.

"Importantly, in 2014 we plan to have active products in Phase 3 clinical trials in all four core major therapeutic areas of focus: cardiovascular medicine (congestive heart failure), inflammatory/immune diseases (Crohn's disease), orthopedics (spinal fusion and intervertebral disc repair) and oncology (acute Graft versus Host Disease, and cord blood expansion in bone marrow transplantation)."

Existing cash reserves are sufficient to meet current and new product development plans. Cost savings and other synergies are expected across personnel, capital expenditure, and manufacturing, and as a result there will only be a modest increase in operating cash burn.

### Strategic and Financial Benefits of the Transaction

- Significant new and early potential revenue stream with the acquisition of Prochymal®, the world's first approved stem cell therapeutic and the only stem cell therapeutic designated by the United States Food and Drug Administration (FDA) as both an Orphan Drug and Fast Track product. Prochymal® has already received conditional approval in Canada and New Zealand for the treatment of children with acute GvHD, and is available in the United States under an Expanded Access Program for treatment of acute GvHD in both children and adults.
- A broadening of Mesoblast's Phase 3-ready products in two new indications:
  - Crohn's disease a major driver for the transaction was Mesoblast's evaluation of the ongoing, 330-patient, Phase 3 trial in patients with Crohn's disease who have failed other biologic agents. Following an interim analysis for futility after 207 patients were enrolled, the best performing Prochymal dose (based on the primary endpoint of disease remission) was selected to complete the study.
  - Acute GvHD the promising Phase 3 data in adults with GvHD at high risk of death due to liver or gut complications was another major driver for the transaction, and Mesoblast intends to seek approval from the FDA for this indication.
- Expansion into Japan through an existing collaboration with JCR Pharmaceuticals Co. Ltd., which will manufacture and market the cultured MSC product in Japan for acute GvHD. Japan represents a significant market opportunity for both MPC and MSC-based products.
- Acquisition of Osiris' entire MSC intellectual property portfolio, including 110 granted patents globally: 48 in the United States, 21 in Europe and 9 in Japan. The granted patents cover composition of matter, uses and methods claims to 2025. Additional patent applications, if granted, will extend patent protection to 2031. The acquired portfolio is highly complementary and additive to Mesoblast's existing patent estate.
- Ownership of Osiris' extensive long-term clinical data from over 1,500 patients treated with cultured MSCs, including safety, efficacy and repeat dosing data.

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**United States Operations** 

#### **Transaction Terms**

Mesoblast will pay Osiris US\$20 million upon closing of the transaction, with US\$15 million in Mesoblast stock payable upon transfer of the assigned assets. Osiris will receive an additional US\$15 million of cash in 6 months and may receive up to US\$50 million in milestones that are contingent on the successful achievement of future late-stage clinical or regulatory targets (e.g., United States or European product regulatory approvals). All contingent milestones are payable in cash or Mesoblast stock, at Mesoblast's discretion. Osiris may also receive earnout on sales of acquired products, ranging from low single-digit to a 10% cap on annual sales in excess of US\$750 million.

#### **Conference Call Information**

Webcast link - <a href="http://www.brrmedia.com/event/116950/">http://www.brrmedia.com/event/116950/</a>

Conference ID: 729675# Australia Toll Free: 1800 267 430 Australia Local Dial: +61 2 9008 9006 USA/Canada: 1855 881 1339 0053 116 1300 Japan: New Zealand: 0800 441 525 8001 012 821 Singapore: United Kingdom: 0800 016 3843

#### **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 Mesenchymal Precursor Cell (MPC) technology platform, its culture-expanded Mesenchymal Stem Cells (MSCs), Dental Pulp Stem Cells (DPSCs) and expanded Hematopoietic Stem Cells (HSCs). Mesoblast's allogeneic or 'off-the-shelf' regenerative medicine products focus on repair of damaged tissue and modulation of inflammatory responses in conditions with significant unmet medical needs. The lead product candidates use its MPC and MSC platforms in four major and distinct areas - systemic inflammatory conditions, cardiovascular diseases, orthopedic diseases of the spine and oncology conditions. <a href="https://www.mesoblast.com">www.mesoblast.com</a>

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