asx announcement

mesoblast
the regenerative medicine company

# MESOBLAST REPORTS FINANCIAL RESULTS FOR PERIOD ENDED 31 MARCH 2016 AND PROVIDES CORPORATE UPDATE

**Melbourne, Australia (10 May 2016); and New York, USA (9 May 2016):** Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported its consolidated financial results and operational highlights for the third quarter and nine months ended 31 March 2016.

In line with previous guidance, the Company has maintained a significantly reduced operating cash burn. Substantial progress has been made in the Company's Tier 1 clinical programs, which brings these product candidates closer to market and supports potential new strategic collaborations.

## Financial Highlights

At 31 March 2016, the Company had cash reserves of US$100 million.

Operating cash outflow for the third quarter of 2016 was US$22 million. The total cash outflows of both the second and third quarters of 2016 was US$42 million, a reduction of 25% in comparison to the total outflows of both the first quarter of 2016 and the fourth quarter of 2015 of US$55 million.

For the nine months ended 31 March 2016, the Company's loss before income tax improved by 14% (US$9 million) as compared to the comparative period in FY2015. The main items within this overall loss reduction, which impacted our cash reserves, were a 19% reduction in research and development expenses and a 21% reduction in management and administration costs.

## Operational Highlights

- MPC-150-IM for advanced heart failure: The Phase 3 trial is recruiting well across North America, and is expanding to Europe this quarter.
    - Phase 3 trial was significantly reduced from 1,165 to 600 subjects following FDA meeting.
    - The trial's primary endpoint is a comparison of recurrent heart failure related major adverse cardiac events (HF-MACE) between treated patients and controls.
    - The trial's Data Monitoring Committee (DMC) convened in April 2016. After reviewing the clinical data from the trial's first 175 patients, the DMC recommended that the study should continue according to its protocol.
- MPC-06-ID for chronic low back pain: The current 360 patient Phase 3 trial continues to expand across US sites.
    - In line with FDA written guidance, the trial uses a composite primary endpoint with thresholds for pain and function and a follow up period of 24 months.
- MPC-300-IV for biologic-refractory rheumatoid arthritis: Top-line Phase 2 results released from the first cohort of rheumatoid arthritis patients who have previously failed one or more biologic agents showed that a single intravenous infusion of the lower dose of MPC-300-IV resulted in early and sustained clinical responses, with no cell-related adverse events.


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- TEMCELL: Mesoblast's licensee in Japan, JCR Pharmaceuticals Co. Ltd. (JCR), launched the first fully-approved allogeneic regenerative medicine in Japan, TEMCELL® HS Inj. (TEMCELL) for acute Graft Versus Host Disease (aGVHD) in children and adults in Q3 FY2016.

    - Japan's National Health Insurance has set reimbursement for TEMCELL at ¥868,680 (approximately US$8,100) for 72 million cells.

    - A four-week, multi-dose treatment course of TEMCELL for an average adult is expected to be reimbursed at ¥13,898,880 (approximately US$130,000), or at ¥20,848,320 (approximately US$195,000) if symptoms persist and additional dosing is required.

    - Mesoblast is entitled to receive royalties and other payments at pre-defined thresholds of net sales, first royalties recognized in Q3 FY2016.

- MSC-100-IV for steroid-refractory aGVHD: Results from 241 children treated in an Expanded Access Program for children with steroid-refractory aGVHD, conducted across more than 50 sites in North America and globally, demonstrated clinically meaningful responses associated with significantly increased survival.

    - Mesoblast is recruiting an open-label single Phase 3 trial in 60 children with aGVHD as first-line therapy after steroid failure.

**Public Presentations and Peer Reviewed Articles**

- MPC-150-IM and MPC-300-IV: Phase 2 trial results in CHF and Type 2 Diabetes were published in leading peer reviewed journals, *Circulation Research* and *Diabetes Care*, respectively.

- Technology developed at Harvard University and exclusively licensed by Mesoblast was shown in a preclinical study in the journal *Stem Cells* to enhance homing properties of mesenchymal lineage cells to sites of inflammation and to induce durable reversal of Type 1 diabetes.

- MSC-100-IV: Data from 241 children presented at the tandem annual scientific meetings of the Center for International Blood & Marrow Transplant Research and the American Society of Blood and Marrow Transplantation in Hawaii in February. These data were also presented at the third International Conference on Regenerative Medicine held within the Vatican in April.

- MPC-75-IA: Results released from our Phase 2a trial in patients with post-traumatic knee injury to the anterior cruciate ligament, which showed that a single intra-articular injection of our MPC product candidate, resulted in improvement in pain, function, cartilage thickness, and joint structure over 24 months. The study results were presented at 2016 Osteoarthritis Research Society International World Congress in The Netherlands, in March.

**Financial Results for the three months ended 31 March 2016 (the third quarter) (in USD)**

Loss before income tax improved by 5% for the third quarter of 2016 compared with the third quarter of 2015. Within this overall loss reduction, the main items which impacted our cash reserves were as follows:

- **Revenue:** Revenue was $4.1 million for the third quarter of 2016 compared with $4.2 million for the third quarter of 2015, a decrease of $0.1 million. This decrease was primarily due to a decrease in interest income as we increased the proportion of cash reserves held in U.S. dollars to reduce currency risk which is offset by the royalty income earned on sales of TEMCELL in Japan since the launch of the product on 24 February 2016 by our licensee, JCR.

- **Research and Development:** Research and development (R&D) expenses were $12.0 million for the third quarter of 2016 compared with $13.4 million for the third quarter of 2015, a decrease of $1.4 million. This decrease primarily reflects a reduction in expenditures of our Tier 2 products and product support costs as management reduced costs in line with our corporate strategy.

- **Manufacturing Commercialization:** Manufacturing commercialization expenses were $7.7 million for the third quarter of 2016 compared with $5.3 million for the third quarter of 2015, an increase of $2.4 million. This increase was primarily driven by an increase in the number of production runs to meet the clinical supply demands of our Tier 1 products and preparing the facility for commercialization.

- **Management and Administration:** Management and administration expenses were $5.4 million for the third quarter of 2016 compared with $6.7 million for the third quarter of 2015, a decrease of $1.3 million. This decrease was primarily due to lower share based payment expenses and favourable exchange rate movements as the U.S. dollar strengthened against the Australian dollar. The majority of management and administration expenses were incurred in Australian dollars.

The overall loss reduction before income tax also includes reduction in items which did not impact our current cash reserves, such as: fair value measurement of contingent consideration, foreign exchange movement within other operating income and expenses and finance costs. Our net loss attributable to ordinary shareholders was $16.9 million, or 4.49 cents per share, for the third quarter of 2016, compared with $22.2 million, or 7.00 cents per share, for the third quarter of 2015.

**Financial Results for the nine months ended 31 March 2016 (the nine months) (in USD)**
Loss before income tax improved by 14% for the nine months of 2016 compared with the nine months of 2015. Within this overall loss reduction, the main items which impacted our cash reserves were as follows:

- **Revenue:** Revenue was $15.7 million for the nine months of 2016 compared with $15.6 million for the nine months of 2015, an increase of $0.1 million. This increase was primarily due to higher milestone revenue received during the nine months of 2016 compared with the nine months of 2015 and royalty income earned on sales of TEMCELL. This is offset by a decrease in interest income as we increased the proportion of cash reserves held in U.S. dollars to reduce currency risk

- **Research and Development:** R&D expenses were $35.6 million for the nine months of 2016 compared with $44.2 million for the nine months of 2015, a decrease of $8.6 million. This decrease primarily reflects a reduction in expenditures of our Tier 2 products and product support costs as management reduced costs in line with our corporate strategy.

- **Manufacturing Commercialization:** Manufacturing commercialization expenses were $22.0 million for the nine months of 2016 compared with $16.8 million for the nine months of 2015, an increase of $5.2 million. This increase was primarily driven by our increased production runs to meet the clinical supply demands of our Tier 1 products.

- **Management and Administration:** Management and administration expenses were $16.7 million for the nine months of 2016 compared with $21.2 million for the nine months of 2015, a decrease of $4.5 million. This decrease was primarily due to lower share based payment expenses, a reduction in legal and professional advisor activities and favourable exchange rate movements as the U.S. dollar strengthened against the Australian dollar. The majority of management and administration expenses were incurred in Australian dollars.

The overall loss reduction before income tax also includes reduction in items which did not impact our current cash reserves, such as: fair value measurement of contingent consideration, foreign exchange movement within other operating income and expenses and finance costs. Our net loss attributable to ordinary shareholders was $52.4 million, or 14.76 cents per share, for the nine months of 2016, compared with $65.7 million, or 20.68 cents per share, for the nine months of 2015.

**2016 Financial Guidance**

Mesoblast maintains last quarter's guidance, namely that quarterly operating cash burn will reduce by approximately 20-25% in comparison with Q1 FY2016 / Q4 FY2015 while still achieving timelines for important value inflexion points for our heart failure, back pain and rheumatoid arthritis programs, and to file with the FDA for approval of our paediatric aGVHD product candidate.

**Conference Call Details**

Australia: 9:00 am AEDT on Tuesday, 10 May 2016 1800 558 698 and 1800 809 971 (toll-free Australia)
USA: 7:00 pm ET on Monday, 9 May 2016 1855 8811 339 (toll-free US)
Ex USA and Australia: +612 9007 3187

Passcode: 762609

The live webcast can be accessed via
http://webcasting.brrmedia.com/broadcast/5652364ab9ebca62060cb159

The archived webcast will be available in the Events and Presentations section of the Investor page in the Mesoblast website.

**About Mesoblast**

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a global leader in developing innovative cell-based medicines. 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, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

**Forward Looking Statements**

This press release contains forward-looking statements which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on estimates and information available to us at the time of this press release and are not guarantees of future performance. Statements in this release involve risks, uncertainties and assumptions. If the risks or uncertainties ever materialize or the assumptions prove incorrect, our results may differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact could be deemed forward-looking statements, including, but not limited to: the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development programs; our ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; our ability to advance our manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of our product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for our product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and our ability to enter into and maintain established strategic collaborations; our ability to establish and maintain intellectual property on our product candidates and our ability to successfully defend these in cases of alleged infringement; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; our financial performance; developments relating to our competitors and our industry; and the pricing and reimbursement of our product candidates, if approved.

Additional risks and uncertainties that could affect Mesoblast's financial results are included under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in the Mesoblast's most recent filings with the SEC, which are available on Mesoblast's website at http://www.mesoblast.com in the Investors and Media section and on the SEC's website at www.sec.gov. Additional information will also be set forth in other filings that the Company makes with the SEC from time to time. All forward-looking statements in this press release are based on information available to the Company as of the date hereof, and Mesoblast does not assume any obligation to update the forward-looking statements provided to reflect events that occur or circumstances that exist after the date on which they were made.

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## Consolidated Income Statement (unaudited)

| (in thousands, except per share amount) | Three Months Ended March 31, 2016 | 2015 | Nine Months Ended March 31, 2016 | 2015 |
|---|---|---|---|---|
| Revenue | 4,142 | 4,242 | 15,669 | 15,585 |
| Research & development | (12,015) | (13,442) | (35,618) | (44,174) |
| Manufacturing commercialization | (7,721) | (5,307) | (22,042) | (16,757) |
| Management and administration | (5,413) | (6,734) | (16,666) | (21,219) |
| Fair value remeasurement of contingent consideration | 1,826 | (2,792) | 6,097 | (7,275) |
| Other operating income and expenses | 547 | 3,982 | 2,891 | 14,961 |
| Finance costs | (2,489) | (2,191) | (6,939) | (6,788) |
| **Loss before income tax** | **(21,123)** | **(22,242)** | **(56,608)** | **(65,667)** |
| Income tax benefit/(expense) | 4,190 | — | 4,190 | — |
| **Loss attributable to the owners of Mesoblast Limited** | **(16,933)** | **(22,242)** | **(52,418)** | **(65,667)** |
| **Losses per share from continuing operations attributable to the ordinary equity holders of the Group:** | **Cents** | **Cents** | **Cents** | **Cents** |
| Basic - losses per share | (4.49) | (7.00) | (14.76) | (20.68) |
| Diluted - losses per share | (4.49) | (7.00) | (14.76) | (20.68) |

## Consolidated Statement of Comprehensive Income (unaudited)

| (in thousands) | Three Months Ended March 31, 2016 | 2015 | Nine Months Ended March 31, 2016 | 2015 |
|---|---|---|---|---|
| **(Loss)/profit for the year** | **(16,933)** | **(22,242)** | **(52,418)** | **(65,667)** |
| **Other comprehensive income** | | | | |
| *Items that may be reclassified to profit and loss* | | | | |
| Changes in the fair value of available-for-sale financial assets | 36 | — | (148) | — |
| Exchange differences on translation of foreign operations | 1,527 | (7,098) | (324) | (26,677) |
| Other comprehensive (loss)/income for the period, net of tax | **1,563** | **(7,098)** | **(472)** | **(26,677)** |
| **Total comprehensive (loss)/income is attributable to the owners of Mesoblast Limited** | **(15,370)** | **(29,340)** | **(52,890)** | **(92,344)** |


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## Consolidated Statement of Balance Sheet
## (unaudited)

| (in thousands) | As of March 31, 2016 | As of June 30, 2015 |
|---|---|---|
| **Assets** | | |
| **Current Assets** | | |
| Cash & cash equivalents | 99,929 | 110,701 |
| Trade & other receivables | 8,108 | 3,972 |
| Prepayments | 4,093 | 7,787 |
| **Total Current Assets** | **112,130** | **122,460** |
| | | |
| **Non-Current Assets** | | |
| Property, plant and equipment | 3,439 | 4,398 |
| Available-for-sale financial assets | 2,152 | 2,300 |
| Other non-current assets | 2,366 | 2,367 |
| Intangible assets | 650,055 | 650,241 |
| **Total Non-Current Assets** | **658,012** | **659,306** |
| **Total Assets** | **770,142** | **781,766** |
| | | |
| **Liabilities** | | |
| **Current Liabilities** | | |
| Trade and other payables | 23,383 | 28,242 |
| Deferred revenue | 15,004 | 15,004 |
| Provisions | 2,874 | 5,161 |
| **Total Current Liabilities** | **41,261** | **48,407** |
| | | |
| **Non-Current Liabilities** | | |
| Deferred revenue | 11,252 | 22,505 |
| Deferred tax liability | 145,197 | 149,387 |
| Provisions | 93,497 | 93,480 |
| **Total Non-Current Liabilities** | **249,946** | **265,372** |
| **Total Liabilities** | **291,207** | **313,779** |
| **Net Assets** | **478,935** | **467,987** |
| | | |
| **Equity** | | |
| Issued Capital | 770,301 | 709,191 |
| Reserves | 25,012 | 22,756 |
| (Accumulated losses)/retained earnings | (316,378) | (263,960) |
| **Total Equity** | **478,935** | **467,987** |


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## Consolidated Statement of Cash Flows
## (unaudited)

| (in thousands) | Nine months ended March 31, 2016 | 2015 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Milestone payment received | 3,500 | 2,000 |
| Research and development tax incentive received | — | 1 |
| Payments to suppliers and employees (inclusive of goods and services tax) | (74,223) | (78,418) |
| Interest received | 816 | 2,645 |
| Other income received | — | 184 |
| Income taxes (paid)/refunded | — | (68) |
| **Net cash (outflows) in operating activities** | **(69,907)** | **(73,656)** |
| | | |
| **Cash flows from investing activities** | | |
| Payments for financial derivatives | — | (851) |
| Payments for investments | (805) | — |
| Payments for licenses | (200) | (70) |
| Investment in fixed assets | (680) | (1,939) |
| Payments for rental deposits | — | (443) |
| **Net cash (outflows) in investing activities** | **(1,685)** | **(3,303)** |
| | — | |
| **Cash flows from financing activities** | | |
| Proceeds from issue of shares | 68,549 | 1,056 |
| Payments for share issue costs | (6,501) | — |
| **Net cash inflows by financing activities** | **62,048** | **1,056** |
| | | |
| Net (decrease)/increase in cash and cash equivalents | (9,544) | (75,903) |
| Cash and cash equivalents at beginning of period | 110,701 | 185,003 |
| FX (losses)/gains on the translation of foreign bank accounts | (1,228) | (14,399) |
| **Cash and cash equivalents at end of period** | **99,929** | **94,701** |


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