asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS FOR THE THREE MONTHS AND FOR THE YEAR ENDED 30 JUNE 2016

Melbourne, Australia; and New York, USA; August 25, 2016: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported its consolidated financial results and operational highlights for the three months ended 30 June 2016 (fourth quarter of 2016) and year ended 30 June 2016 (FY16).

Mesoblast ended FY16 with cash reserves of US$80.9 million. The Company reduced its annual operating and investing cash outflows by 15% (US$16.4 million) to US$89.7 million for FY16 in comparison with the prior financial year. Additionally, Mesoblast outlined cost-cutting measures to further reduce cash burn by up to US$25 million in the year ended 30 June 2017 (FY17) in order to absorb the incremental costs of the heart failure program.

Mesoblast Chief Executive Silviu Itescu said: "During the past financial year, we have made a concerted effort to significantly reduce our cash burn and to apply our resources prudently to advance our Tier 1 product candidates towards major upcoming value inflexion points. Consistent signals of efficacy using our cells in the hardest to treat patient segments across multiple disease states continue to validate the disruptive potential of our platform technology."

Key Progress in Operations

- Phase 3 trials in chronic heart failure (CHF) and chronic low back pain due to degenerative disc disease (CLBP) recruiting toward major milestones
- Phase 3 trial in steroid-refractory acute Graft Versus Host Disease (aGVHD) recruiting towards completion
- Positive Phase 2 trial in biologic refractory rheumatoid arthritis (RA) patients opens new blockbuster opportunity
- Phase 2 trial results across multiple Tier 1 product candidates were highlighted in peer-reviewed publications and presentations
- Manufacturing achievements in formulation and yield underpin future commercial rollouts
- Continued expansion of our IP portfolio to 728 patents or patent applications across 72 families provides broad commercial protection for our cell based product candidates

FY17 Outlook

- Material steps taken to conserve cash and rebalance organization to focus on delivery of Tier 1 outcomes
- Upcoming significant Phase 3 milestones for Tier 1 product candidates
- With control of our valuable heart failure product candidate, the Company can refine the clinical pathway to global commercialization
- Enhanced opportunities for partnering based on cumulative Phase 2/3 clinical results
- Expanding US investor base provides additional liquidity

Financial Highlights

Mesoblast ended FY16 with cash reserves of US$80.9 million.

The Company reduced its annual operating and investing cash outflows by 15% (US$16.4 million) to US$89.7 million for the FY16 in comparison with FY15, primarily by decreasing Tier 2 expenditure, lower payments to 3rd parties and reduced employee costs.

For FY17 the Company expects to save a further US$20-25 million in operating cash outflows compared with FY16 in order to absorb the incremental costs of the MPC-150-IM program in FY17. Anticipated total trial costs for MPC-150-IM are approximately $13 million to the scheduled Interim Analysis in Q1 2017.

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As previously announced, a fully discretionary equity facility has been established for up to $A120 million/$US90 million over 36 months to provide additional funds as required.

Operational Streamlining for FY17

As previously indicated in July, the Company has initiated a number of cost reductions in order to fund the incremental costs of the MPC-150-IM program in FY17.

Specifically:

- Company labor force was restructured in July 2016 with a significant number of roles eliminated in line with focus on Tier 1 products
- Third party vendor costs, consultancy costs and activities have been reduced
- Reductions to office accommodation and laboratory space have been executed
- Enrollment has been completed for our heart attack study using MPC-25-IC, reducing future expenditure on this Tier 2 program
- Certain Tier 2 programs have been deprioritized (MPC-MICRO-IO and MPC-CBE)

Operational Highlights

Significant progress has been made in four Tier 1 clinical programs, with three in Phase 3 and one in Phase 2. Each of the three Phase 3 trials have major value inflexion points reading out in FY17. The CHF, RA and CLBP product candidates using the Company's proprietary allogeneic Mesenchymal Precursor Cells (MPCs) all have blockbuster potential and are well positioned to advance through strategic partnerships through confirmatory studies to registration. Mesoblast intends to take its product candidate for aGVHD, MSC-100-IV, to licensure directly.

MPC-150-IM for Advanced Heart Failure:

The Phase 3 trial for 600 patients with advanced heart failure is recruiting well across North American sites; as of June over 240 patients had been enrolled.

After reviewing all clinical data for the first 175 patients in April 2016, the trial's Data Monitoring Committee recommended that the study should continue according to its protocol.

Based on observed HF-MACE event rates in the trial to date, the Company has decided to bring forward to Q1 2017 a previously planned Interim Analysis to assess the trial's primary endpoint between cell-treated and control patients. Anticipated costs are US$13 million to this time point.

Interim analysis results will provide evidence based support for strategic and scientific decisions regarding the Phase 3 program.

MPC-300-IV for Biologic Refractory Rheumatoid Arthritis:

The Phase 2 trial in biologic refractory rheumatoid arthritis has completed enrollment and results of the 12 week primary endpoint were released in August 2016. An intravenous infusion of allogeneic MPCs was well tolerated in biologic refractory RA patients, without serious adverse events over 12 weeks.

A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, and disease activity, with the 2 million MPCs/kg dose providing the greatest benefit.

The responses to date in this 48-patient, randomized, placebo-controlled Phase 2 trial provide support for the potential of Mesoblast's allogeneic MPCs to be positioned as first-line treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent.

MPC-06-ID for Chronic Low Back Pain Due to Degenerative Disc Disease:

The current 360 patient Phase 3 trial is recruiting well across US sites.

The FDA has provided written guidance, specifically:

- Use of a composite primary endpoint is acceptable for approval
- Agreed thresholds for pain (50% decrease in VAS) and function (15 point improvement in ODI)
- Two time points (12 and 24 months) for meeting pain and functional improvement criteria
- No intervention at the treated level through 24 months

The Company intends to conduct an interim analysis in the Phase 3 trial in Q1 CY 2017.

***MSC-100-IV for Steroid Refractory Acute Graft Versus Host Disease*:**

MSC-100-IV is currently being evaluated in a 60-patient Phase 3 registration trial in the US as first-line therapy after steroid failure in children with aGVHD.

The open-label trial, if successful, will support filing of a biologic license application to the FDA for regulatory approval.

The Company plans to conduct a futility analysis in Q4 CY 2016.

TEMCELL® HS Inj.: Mesoblast's licensee in Japan, JCR Pharmaceuticals Co. Ltd. (JCR), launched its culture-expanded Mesenchymal Stem Cell product, TEMCELL® HS Inj., in February 2016 for aGVHD. It is the first fully-approved allogeneic regenerative medicine in Japan.

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

Selected 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.

- 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-06-ID: 24-month data were presented and received the 2016 Best Basic Science Abstract Award at the 24th Annual Scientific sessions of the Spine Intervention Society meeting in August.

- 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 the 2016 Osteoarthritis Research Society International World Congress in The Netherlands in April.

- Technology developed at Harvard University and exclusively licensed by Mesoblast was shown in a preclinical study, published 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.

Financial Results for the Three Months Ended 30 June 2016 (Fourth Quarter of 2016)

Loss before income tax increased by 12% for the fourth quarter of 2016 compared with the three months ended 30 June 2015 (fourth quarter of 2015). There were a number of significant non-cash items within this overall loss increase. However those which impacted our cash reserves were:

- **Revenue:** Revenue was US$26.9 million for the fourth quarter of 2016 compared with US$4.2 million for the fourth quarter of 2015, an increase of US$22.7 million. This increase was primarily due to the non-cash recognition of US$22.5 million of deferred revenue in this period as we regained full world-wide rights from Teva on our product candidate MPC-150-IM in June 2016. Included in the increase was royalty income earned on sales of TEMCELL in Japan since the launch of the product on 24 February 2016 by our licensee, JCR, which is offset by a decrease in interest income as we increased the proportion of cash reserves held in US dollars to reduce currency risk.

  All deferred revenue amounts are non-cash. Our cash reserves experienced a net reduction in relation to receipts from revenues in the fourth quarter of 2016 compared with the fourth quarter of 2015 of US$0.2 million as the increased royalties were more than offset by the shortfalls in interest income receipts.

- **Research and Development:** Research and development (R&D) expenses were US$14.4 million for the fourth quarter of 2016 compared with US$18.5 million for the fourth quarter of 2015, a decrease of US$4.1 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 US$7.7 million for the fourth quarter of 2016 compared with US$7.0 million for the fourth quarter of 2015, an increase of US$0.7 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 US$5.8 million for the fourth quarter of 2016 compared with US$8.3 million for the fourth quarter of 2015, a decrease of US$2.5 million. This decrease was primarily due to a savings in labour and associated costs and a reduction in consultancy expenses as management reduced costs in line with our corporate strategy.

The overall loss reduction before income tax also includes reductions in items which did not impact our current cash reserves, such as: fair value remeasurement of contingent consideration, impairment of intangible assets, foreign exchange movements within other operating income and expenses and finance costs.

Our net profit attributable to ordinary shareholders was US$48.3 million, or US 12.78 cents earnings per share, for the fourth quarter of 2016, compared with a net loss of US$30.6 million, or US 9.24 cents losses per share, for the fourth quarter of 2015.

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Financial Results for the Year Ended 30 June 2016

Loss before income tax reduced by 6% for FY16 compared with the fiscal year ended 30 June 2015 (FY15). There were a number of significant non-cash items within this overall loss reduction however those which impacted our cash reserves, were:

- **Revenue:** Revenue was US$42.5 million for FY16 compared with US$19.8 million for FY15, an increase of US$22.7 million. This increase was primarily due to the non-cash recognition of US$22.5 million of deferred revenue in the fourth quarter of 2016 as we regained full world-wide rights from Teva on our product candidate MPC-150-IM in June 2016.

  All deferred revenue amounts are non-cash. Higher milestone revenue was received during FY16 compared with FY15 as well as first royalty income earned on sales of TEMCELL since the launch of the product on 24 February 2016 by our licensee, JCR. This increase in revenue was offset by a decrease in interest income as we increased the proportion of cash reserves held in U.S. dollars to reduce currency risk. Overall, cash reserves received a net benefit of US$0.2 million from revenue in FY16 compared with FY15.

- **Research and Development:** R&D expenses were US$50.0 million for FY16 compared with US$62.6 million for FY15, a decrease of US$12.6 million. This decrease primarily reflects a reduction in expenditures on our Tier 2 products and product support costs as management reduced costs in line with our corporate strategy.

- **Manufacturing Commercialization:** Manufacturing commercialization expenses were US$29.8 million for FY16 compared with US$23.8 million for FY15, an increase of US$6.0 million. This increase was primarily driven by our increased 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 US$22.5 million for FY16 compared with US$29.5 million for FY15, a decrease of US$7.0 million. This decrease was primarily due to a savings in labor and associated costs, a reduction in legal and professional advisor fees and favourable exchange rate movements as the U.S. dollar strengthened against the Australian dollar. The majority of our management and administration expenses were incurred in Australian dollars.

The overall loss reduction before income tax also includes reductions in items which did not impact our current cash reserves, such as: fair value remeasurement of contingent consideration, impairment of intangible assets, foreign exchange movement within other operating income and expenses and finance costs.

Our net loss attributable to ordinary shareholders was US$4.1 million, or US 1.14 cents per share, for the 12 months of 2016, compared with US$96.2 million, or US 29.99 cents per share, for the 12 months of 2015.

Conference Call Details

Australia: 9:00 am AEDT on Thursday 25 August, 2016

T: 1800 558 698 and 1800 809 971 (toll-free Australia)

USA: 7:00 pm ET on Wednesday August 24, 2016
T: 1855 8811 339 (toll-free US)

Ex USA and Australia: +612 9007 3187

Passcode: 262443

The live webcast can be accessed via http://webcasting.boardroom.media/broadcast/578ebfb7147cda9d5dbf5728
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 includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

For further information, please contact:

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Consolidated Income Statement

(in thousands, except per share amount)	(unaudited) Three Months Ended June 30, 2016	2015	(audited) Year Ended June 30, 2016	2015
Revenue	26,879	4,176	42,548	19,761
Research & development	(14,395)	(18,476)	(50,013)	(62,649)
Manufacturing commercialization	(7,721)	(7,026)	(29,763)	(23,783)
Management and administration	(5,834)	(8,318)	(22,500)	(29,540)
Fair value remeasurement of contingent consideration	31,326	445	37,423	(6,830)
Impairment of intangible assets	(61,919)	-	(61,919)	—
Other operating income and expenses	(177)	340	2,714	15,303
Finance costs	(2,372)	(1,719)	(9,311)	(8,506)
Loss before income tax	**(34,213)**	**(30,578)**	**(90,821)**	**(96,244)**
Income tax benefit/(expense)	82,504	—	86,694	—
Profit/(loss) attributable to the owners of Mesoblast Limited	**48,291**	**(30,578)**	**(4,127)**	**(96,244)**
Earnings/(losses) per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - earnings/(losses) per share	12.78	(9.24)	(1.14)	(29.99)
Diluted - earnings/(losses) per share	12.78	(9.24)	(1.14)	(29.99)

Consolidated Statement of Comprehensive Income

(in thousands)	(unaudited) Three Months Ended June 30, 2016	2015	(audited) Year Ended June 30, 2016	2015
Profit/(loss) for the year	**48,291**	**(30,578)**	**(4,127)**	**(96,244)**
Other comprehensive income				
Items that may be reclassified to profit and loss				
Changes in the fair value of available-for-sale financial assets	(186)	—	(334)	—
Exchange differences on translation of foreign operations	(381)	848	(705)	(25,783)
Other comprehensive (loss)/income for the period, net of tax	**(567)**	**848**	**(1,039)**	**(25,783)**
Total comprehensive income/(loss) is attributable to the owners of Mesoblast Limited	**47,724**	**(29,730)**	**(5,166)**	**(122,027)**

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Consolidated Statement of Balance Sheet (audited)

(in thousands)	As of June 30, 2016	2015
Assets		
Current Assets		
Cash & cash equivalents	80,937	110,701
Trade & other receivables	4,054	3,972
Prepayments	3,832	7,787
Total Current Assets	**88,823**	**122,460**
Non-Current Assets		
Property, plant and equipment	3,063	4,398
Available-for-sale financial assets	1,966	2,300
Other non-current assets	2,343	2,367
Intangible assets	587,823	650,241
Total Non-Current Assets	**595,195**	**659,306**
Total Assets	**684,018**	**781,766**
Liabilities		
Current Liabilities		
Trade and other payables	27,155	28,242
Deferred revenue	—	15,004
Provisions	2,260	5,161
Total Current Liabilities	**29,415**	**48,407**
Non-Current Liabilities		
Deferred revenue	—	22,505
Deferred tax liability	62,693	149,387
Provisions	63,749	93,480
Total Non-Current Liabilities	**126,442**	**265,372**
Total Liabilities	**155,857**	**313,779**
Net Assets	**528,161**	**467,987**
Equity		
Issued Capital	770,272	709,191
Reserves	25,976	22,756
(Accumulated losses)/retained earnings	(268,087)	(263,960)
Total Equity	**528,161**	**467,987**

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Consolidated Statement of Cash Flows
(audited)

(in thousands)	Year ended June 30, 2016	2015
Cash flows from operating activities		
Commercialization revenue received	99	—
Milestone payment received	3,500	2,000
Research and development tax incentive received	4,466	4,456
Payments to suppliers and employees (inclusive of goods and services tax)	(97,190)	(106,760)
Payments for fair value adjustments to contingent consideration subsequent to the business combination measurement period	—	(4,112)
Interest received	1,129	3,043
Other income received	—	405
Income taxes (paid)/refunded	—	(68)
Net cash (outflows) in operating activities	**(87,996)**	**(101,036)**
Cash flows from investing activities		
Payments for financial derivatives	—	(851)
Payments for business combination	—	(2,086)
Payments for investments	(805)	—
Payments for licenses	(200)	(195)
Investment in fixed assets	(722)	(2,204)
Payments for rental deposits	—	272
Receipts from repayments of loans from employees	—	—
Net cash (outflows) in investing activities	**(1,727)**	**(5,064)**
Cash flows from financing activities		
Proceeds from issue of shares	68,549	46,291
Payments for share issue costs	(6,483)	(439)
Net cash inflows by financing activities	**62,066**	**45,852**
Net (decrease)/increase in cash and cash equivalents	(27,657)	(60,248)
Cash and cash equivalents at beginning of period	110,701	185,003
FX (losses)/gains on the translation of foreign bank accounts	(2,107)	(14,054)
Cash and cash equivalents at end of period	**80,937**	**110,701**

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