asx announcement

mesoblast
the regenerative medicine company

MESOBLAST OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR THE FIRST QUARTER ENDED SEPTEMBER 30, 2017

Melbourne, Australia; November 15, 2017; and New York, USA, November 14, 2017: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today provided the market with an update on its corporate strategy, operational highlights, and consolidated financial results for the three months ended September 30, 2017 (first quarter of FY2018).

At September 30, 2017, the Company had cash reserves of US$62.9 million. Cash outflows from operating activities were reduced by US$0.5m (2.3%) for the quarter as compared to the three months ended September 30, 2016 (first quarter of FY2017).

Based on cumulative clinical results to date and the serious and life-threatening nature of the diseases being targeted, the Company believes that its Phase 3 product candidates for acute graft versus host disease (aGVHD), chronic heart failure, and chronic low back pain may represent a paradigm shift in the treatment of these conditions which can lead to earlier market entry due to opportunities afforded by the United States 21st Century Cures Act.

The Company continues to have an active and ongoing strategy to partner one or more of its four Tier 1 product candidates. Fundamental to this strategy is to conclude partnership transactions with those organizations that will deliver the best short and long term outcomes for the company and maximize shareholder value.

Operational Highlights

MSC-100-IV for Acute Graft Versus Host Disease (aGVHD):

Mesoblast's proprietary allogeneic cell therapy MSC-100-IV is being evaluated in a single, open-label Phase 3 trial in up to 60 patients for product registration. This trial continues to recruit across multiple sites in North America and completion of enrollment is imminent. The goal of this trial is to obtain FDA approval in children with steroid-refractory (SR) aGVHD and then pursue label extension to adults.

The Company's GVHD strategy is based on:

- extensive clinical safety and efficacy data generated and published with MSC-100-IV in children with this life-threatening condition;
- the potential for a shortened FDA approval pathway due to the existing fast-track designation for MSC-100-IV;
- a targeted product launch strategy requiring minimal investment; and
- the ability to seek label extension to adults with high-risk steroid refractory aGVHD (liver/gut disease) and product lifecycle management to include chronic GVHD.

MPC-150-IM for Chronic Heart Failure (CHF):

Mesoblast's proprietary allogeneic cell therapy MPC-150-IM is in late-stage clinical development in two randomized controlled trials that target, respectively, advanced and end-stage CHF. The Phase 3 trial in advanced heart failure continues to recruit across multiple sites in North America, with more than 400 of the anticipated approximately 600 NYHA Class II/III CHF patients randomized to date.

During this current quarter, the Company was pleased to report completion of enrollment in the 159-patient randomized, placebo-controlled Phase 2b trial funded by the National Institutes of Health (NIH) and the Canadian

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
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Victoria Australia

T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
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USA

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F +1 212 880 2061

Asia
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#05-01 Centros
Biopreneur 3
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F +65 6570 0176

Institute for Health Research (CIHR) evaluating the Company's proprietary allogeneic mesenchymal precursor cell (MPC) product candidate MPC-150-IM in end-stage heart failure patients with left ventricular assist devices (LVAD).

The Company believes that:

- the LVAD market may represent an early market entry opportunity for MPC-150-IM in end-stage heart failure patients through potential to reduce LVAD morbidity, increase survival and increase LVAD use as destination therapy;
- targeted product launch strategy requires minimal investment;
- by strengthening native heart muscle, Bridge to Recovery (BTR) represents a potential high-growth market opportunity for temporary LVAD use and explantation in end-stage or Class IV heart failure patients; and
- there may be an opportunity to bridge to the larger Class III heart failure population by label extension on obtaining positive Phase 3 trial results.

MPC-06-ID for Chronic Low Back Pain (CLBP):

Mesoblast's proprietary allogeneic cell therapy MPC-06-ID is being evaluated in a 360-patient Phase 3 trial in patients with CLBP who have failed conservative measures. The trial is expected to complete enrollment in early Q1 CY18.

If the Phase 2 results, which showed durable improvement in pain and function from a single intra-discal injection, are confirmed in the Phase 3 trial, the Company believes that MPC-06-ID:

- has the potential to reduce and/or eliminate the need for opioids in the treatment of CLBP; and
- is well positioned to meet the objectives of the 21st Century Cures Act, which includes measures to combat opioid dependence and provide accelerated approval pathways for non-opioid pain reducing drugs.

Over 33,000 people in the United States died of prescription opioid related overdoses in 2016 and the opioid epidemic has been recently declared a public health emergency by the President of the United States. Given that CLBP accounts for 50% of all opioid prescriptions, a non-opioid solution to this disease is imperative.

MPC-300-IV for Systemic, Immune-mediated Diseases:

MPC-300-IV is our cellular product candidate that responds to inflammatory signals with release of counter-inflammatory factors. It has the potential to treat multiple immune-mediated diseases.

MPC-300-IV has generated positive clinical data across three randomized, placebo-controlled Phase 2 trials in disease states associated with inflammation; type 2 diabetes with inadequate glucose control, diabetic kidney disease, and biologic-refractory rheumatoid arthritis (RA).

Results from a 48-patient randomized, placebo-controlled Phase 2 trial in patients with biologic refractory RA over 52 weeks were recently presented at the 2017 American College of Rheumatology Annual Meeting in San Diego, CA. The primary objective of the study was to evaluate safety and tolerability of a single intravenous infusion in biologic refractory RA patients through a 12-week primary endpoint. Additional objectives were to evaluate clinical efficacy at the 12-week endpoint and to assess the durability of effects and safety profile over the full 52-week study.

The results showed an early and durable effect from a single infusion of MPC-300-IV in biologic-refractory RA patients. Specifically:

- Infusions were well-tolerated with no treatment-related serious adverse events reported during the 52-week period, and a safety profile over 52 weeks comparable among the placebo and two MPC treatment groups.

- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, disease activity and patient-reported outcomes. Efficacy signals were observed for each of ACR 20/50/70, ACR-N, HAQ-DI, SF-36 and DAS-28 disease activity score.

- The 2 million MPC/kg dose showed the greatest overall treatment responses. Onset of treatment responses occurred as early as 4 weeks, peaked at 12 weeks, were maintained through 39 weeks, and waned by 52 weeks.

- Greatest benefits over 52 weeks were seen in patients who had failed less than three biologics (1-2 biologic sub-group) prior to MPC treatment, identifying this as a potentially optimal target population.

The results of this Phase 2 trial identified a dose-related treatment effect, the earliest onset of the effect, and the durability from a single dose. Given the excellent safety profile, the Company intends to evaluate whether higher MPC doses can achieve even greater rates of low disease activity or remission within the first 12 weeks and beyond. The Company also plans to evaluate whether the observed durable treatment responses can be maintained for the longer term using repeat dose therapy.

Upcoming Milestones

The Company expects multiple key inflection points over the remainder of the 2018 financial year, including:

- completion of enrollment in Q4 CY2017 in the Phase 3 trial evaluating MSC-100-IV in children with aGVHD;
- the trial's 28-day primary endpoint data is expected in Q1 CY2018 and the 100-day survival result is expected in Q2 CY2018;
- completion of enrollment in early Q1 CY2018 in the Phase 3 trial evaluating MPC-06-ID in patients with chronic low back pain;
- the 6-month primary endpoint in Q1 CY2018 for the fully-enrolled Phase 3 trial evaluating MPC-150-IM in NYHA Class IV patients with advanced heart failure, with full 12-month study results expected in Q3 CY2018; and
- completion of enrollment in 2H CY2018 in the Phase 3 trial evaluating MPC-150-IM in NYHA Class III patients with advanced heart failure.

Financial Highlights

At September 30, 2017, the Company had cash reserves of US$62.9 million, inclusive of net financing cash inflows of US$38.4 million as a result of the entitlement offer in September 2017.

Revenues from royalties on sales of TEMCELL® HS Inj. (TEMCELL)[1] by our licensee in Japan, JCR Pharmaceuticals Co., Ltd., increased by US$0.4 million (178%) to US$0.6 million in the first quarter of FY2018 compared with the first quarter of FY2017. In addition, the Company recognized milestone revenue of US$0.5 million on the cumulative sales of TEMCELL in the first quarter of FY2018.

Cash outflows from operating activities for the quarter were reduced by US$0.5m (2.3%), compared to the first quarter of FY2017.

Mesoblast retains an equity facility for up to A$120 million/US$90 million, to be used at its discretion over the next two years to provide additional funds as required.

[1] TEMCELL® HS. Inj. is a registered trademark of JCR Pharmaceuticals Co., Ltd.

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Financial Results for the Three Months Ended September 30, 2017 (first quarter) (in U.S. Dollars)

The Company contained spend whilst increasing its R&D investment in Tier 1 clinical programs by constraining manufacturing production, and management and administration costs. Research and development expenses increased by US$1.4 million (10%), this increase was offset by cost savings of US$2.4 million (73%) for manufacturing and US$0.4 million (8%) for management & administration for the first quarter of FY2018, compared with the first quarter of FY2017.

There was a decrease of US$13.0 million (57%) in the loss before income tax for the first quarter of FY2018, compared with the first quarter of FY2017. This overall decrease in loss before income tax was primarily due to non-cash items that do not affect cash reserves.

The main items which impacted the loss before income tax movement were:

- **Revenues** from royalties on sales of TEMCELL increased by US$0.4 million (178%) in the first quarter of FY2018 compared with the first quarter of FY2017 and the Company recognized milestone revenue of US$0.5 million on the cumulative sales of TEMCELL in the first quarter of FY2018 compared with US$Nil in the first quarter of FY2017.

- **Research and Development** expenses were US$15.4 million for the first quarter of FY2018, compared with US$14.0 million for the first quarter of FY2017, an increase of US$1.4 million (10%) as the Company invested in Tier 1 clinical programs.

- **Manufacturing** expenses were US$0.9 million for the first quarter of FY2018, compared with US$3.3 million for the first quarter of FY2017, a decrease of US$2.4 million (73%) due to a reduction in manufacturing activity because sufficient quantities of clinical grade product were previously manufactured for all ongoing clinical trials.

- **Management and Administration:** expenses were US$5.0 million for the first quarter FY2018, compared with US$5.4 million for the first quarter of FY2017, a decrease of US$0.4 million (8%) primarily due to a decrease of US$0.5 million in corporate overhead expenses such as rent and IT costs.

The overall decrease in loss before income tax also includes movements in other items which did not impact current cash reserves, such as: fair value remeasurement of contingent consideration, and foreign exchange movements within other operating income and expenses. The net loss attributable to ordinary shareholders was US$7.0 million, or 1.60 cents per share, for the first quarter of FY2018, compared with US$19.8 million, or 5.24 cents per share, for the first quarter of FY2017.

Conference Call Details

Mesoblast will be hosting a conference call beginning at 8.30am AEDT on Wednesday November 15, 2017 / 4.30pm ET on Tuesday November 14, 2017. The conference identification code is 303705.

The live webcast can be accessed via: http://webcasting.boardroom.media/broadcast/59ff897e6afa4a0577a982bb

To access the call, please dial:

Australia Toll Free	1 800 558 698
Australia Alternate	1 800 809 971
United States	1 855 881 1339
United Kingdom	0800 051 8245
Japan	0053 116 1281
Singapore	800 101 2785
Hong Kong	800 966 806
International	+61 2 9007 3187

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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. Forward- looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's 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 Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. 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:

Julie Meldrum
Corporate Communications
Mesoblast
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Schond Greenway
Investor Relations
Mesoblast
T: +1 212 880 2060
E: schond.greenway@mesoblast.com

Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended September 30, 2017	2016
Revenue	1,174	395
Research & development	(15,368)	(14,004)
Manufacturing commercialization	(877)	(3,295)
Management and administration	(5,012)	(5,459)
Fair value remeasurement of contingent consideration	9,495	(1,013)
Other operating income and expenses	668	473
Loss before income tax	**(9,920)**	**(22,903)**
Income tax benefit/(expense)	2,898	3,105
Loss attributable to the owners of Mesoblast Limited	**(7,022)**	**(19,798)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(1.60)	(5.24)
Diluted - losses per share	(1.60)	(5.24)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2017	2016
Loss for the year	**(7,022)**	**(19,798)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Changes in the fair value of available-for-sale financial assets	20	31
Exchange differences on translation of foreign operations	(358)	703
Other comprehensive (loss)/income for the period, net of tax	**(338)**	**734**
Total comprehensive loss attributable to the owners of Mesoblast Limited	**(7,360)**	**(19,064)**

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Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of September 30, 2017	As of June 30, 2017
Assets		
Current Assets		
Cash & cash equivalents	62,941	45,761
Trade & other receivables	4,590	3,743
Prepayments	12,796	14,105
Total Current Assets	**80,327**	**63,609**
Non-Current Assets		
Property, plant and equipment	1,636	1,814
Available-for-sale financial assets	2,018	1,997
Other non-current assets	1,930	1,916
Intangible assets	585,987	586,350
Total Non-Current Assets	**591,571**	**592,077**
Total Assets	**671,898**	**655,686**
Liabilities		
Current Liabilities		
Trade and other payables	20,323	21,805
Provisions	2,447	14,865
Total Current Liabilities	**22,770**	**36,670**
Non-Current Liabilities		
Deferred tax liability	46,395	49,293
Provisions	43,143	52,957
Total Non-Current Liabilities	**89,538**	**102,250**
Total Liabilities	**112,308**	**138,920**
Net Assets	**559,590**	**516,766**
Equity		
Issued Capital	878,669	830,425
Reserves	32,845	31,243
(Accumulated losses)/retained earnings	(351,924)	(344,902)
Total Equity	**559,590**	**516,766**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three months ended September 30, 2017	2016
Cash flows from operating activities		
Commercialization revenue received	474	361
Payments to suppliers and employees (inclusive of goods and services tax)	(20,892)	(21,369)
Interest received	63	181
Income taxes (paid)/refunded	(1)	—
Net cash (outflows) in operating activities	**(20,356)**	**(20,827)**
Cash flows from investing activities		
Payments for contingent consideration	(543)	—
Investment in fixed assets	(83)	(290)
Net cash (outflows) in investing activities	**(626)**	**(290)**
Cash flows from financing activities		
Proceeds from issue of shares	40,449	—
Payments for share issue costs	(2,001)	(55)
Net cash inflows/(outflows) by financing activities	**38,448**	**(55)**
Net increase/(decrease) in cash and cash equivalents	17,466	(21,172)
Cash and cash equivalents at beginning of period	45,761	80,937
FX (losses)/gains on the translation of foreign bank accounts	(286)	590
Cash and cash equivalents at end of period	**62,941**	**60,355**

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