asx announcement

mesoblast
the regenerative medicine company

FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS FOR THE THIRD QUARTER ENDED MARCH 31, 2018

Melbourne, Australia; May 31, 2018; and New York, USA, May 30, 2018: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced strong financial results for the nine months ended March 31, 2018 and provided operational highlights for the third quarter ended March 31, 2018.

Key financial results for the nine months ended March 31, 2018

- At March 31, 2018, the Company had cash reserves of US$59.5 million.
- Revenues increased to US$15.6 million, compared with US$1.8 million in the corresponding period of FY2017, an increase of US$13.8 million.
- This increase reflects revenues received from our two licensees, JCR Pharmaceuticals Co Ltd marketing TEMCELL® Hs. Inj. for treatment of acute Graft Versus Host Disease (aGVHD) in Japan, and TiGenix NV/Takeda (Alofisel®), which has central marketing authorization (MA) approval in Europe for the treatment of perianal fistulae.
- Net cash outflows from operating activities in the nine months of FY2018 were reduced by US$17.2 million (24%) compared with the nine months of FY2017.
- The loss after tax in the nine months of FY2018 was significantly reduced by US$35.2 million (71%), from US$49.6 million in the nine months of FY2017 to US$14.5 million.
- During the quarter, Mesoblast established a non-dilutive, four year credit facility with Hercules Capital for up to US$75 million, with US$35.0 million drawn at closing.

Recent operational highlights and anticipated upcoming milestones

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

- The Phase 3 trial successfully met its Day 28 primary endpoint of overall response in the reporting quarter.
- Upcoming Day 100 survival/safety data (Q2 CY18).
- Upcoming Day 180 survival/safety data (Q3 CY18).
- Based on discussions with the FDA, Mesoblast believes that successful results from the completed Phase 3 trial through Day 100, together with Day 180 safety and quality of life parameters in these patients, may provide sufficient clinical evidence for filing for this product candidate in the United States under an accelerated review pathway.

MPC-150-IM for Advanced and End-Stage Heart Failure:

- Upcoming 12 month data read-out for 159 patient trial in End-Stage Heart Failure and LVAD implantation (Q3 CY18).
- Based on prior Phase 2 results, the FDA granted RMAT designation for MPC therapy in this indication in December 2017.
- Phase 3 events-driven trial for Advanced Heart Failure (Class II/III) enrollment completion (H2 CY18).
- Trial received a positive recommendation from the Independent Data Monitoring Committee to continue without modification after an evaluation of clinical data in the first 465 randomized patients.

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MPC-06-ID for Chronic Low Back Pain:

- Our Phase 3 trial in patients with chronic low back pain who have failed all conservative measures has completed enrollment in the reporting quarter.

Continue to access non-dilutive capital for commercialization of MSC-100-IV (remestemcel-L).

Establish U.S., global and regional commercial partnerships for high volume products.

Financial Results for the Three Months Ended March 31, 2018 (third quarter) (in U.S. Dollars)

Revenues were US$1.1 million in the third quarter of FY2018 compared with US$0.9 million in the third quarter of FY2017, an increase of US$0.2 million (19%).

There was an increase of US$11.4 million (116%) in the loss after income tax for the third quarter of FY2018, compared with the third quarter of FY2017.

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

- **Revenues** were US$1.1 million for the third quarter of FY2018, compared with US$0.9 million for the third quarter of FY2017, an increase of US$0.2 million. This increase of US$0.2 million in the third quarter of FY2018 was due to an increase of US$0.7 million from royalties on sales of TEMCELL by our licensee in Japan, JCR, offset by a decrease of US$0.5 million in milestone revenue for TEMCELL, licensed with JCR.

- **Research and Development** expenses were US$16.8 million for the third quarter of FY2018, compared with US$13.9 million for the third quarter of FY2017, an increase of US$2.9 million (21%) as the Company invested in Tier 1 clinical programs.

- **Manufacturing** expenses were US$1.7 million for the third quarter of FY2018, compared with US$3.8 million for the third quarter of FY2017, a decrease of US$2.1 million (55%) following completion, in the prior year, of clinical product necessary for Phase 3 trials.

- **Management and Administration** expenses were US$6.0 million for the third quarter of FY2018, compared with US$5.5 million for the third quarter of FY2017, an increase of US$0.5 million (9%) primarily due to increased corporate activities.

- **Finance Costs** of US$0.4 million in interest expenses were recognized in the third quarter of FY2018 in relation to the Company's loan and security agreement entered into with Hercules in March 2018. No interest expense was recognized in the third quarter of FY2017.

The overall increase in loss after 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.

A non-cash income tax benefit of US$3.4 million was recognized in the third quarter of FY2018 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period, compared to US$3.1 million in the third quarter of FY2017.

The net loss attributable to ordinary shareholders was US$21.1 million, or 4.47 cents loss per share, for the third quarter of FY2018, compared with US$9.8 million, or 2.43 cents loss per share, for the third quarter of FY2017.

At March 31, 2018, the Company had cash reserves of US$59.5 million.

In March 2018, Mesoblast established a non-dilutive, four-year credit facility with Hercules Capital for up to US$75 million with US$35.0 million drawn at closing. An additional US$15.0 million may be drawn on or before Q4 CY2018, and a further US$25.0 million may be drawn on or before Q3 CY2019, in each case as certain milestones are met.

Mesoblast retains an equity facility for up to A$120 million/US$90 million, to be used at its discretion over the next 15 months to provide additional funds as required.

Financial Results for the Nine Months Ended March 31, 2018 (the nine months) (in U.S. Dollars)

Revenues were US$15.6 million in the nine months of FY2018 compared with US$1.8 million in the nine months of FY2017, an increase of US$13.8 million.

There was a decrease of US$35.2 million (71%) in the loss after income tax for the nine months of FY2018, compared with the nine months of FY2017.

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

- **Revenues** were US$15.6 million for the nine months of FY2018, compared with US$1.8 million for the nine months of FY2017, an increase of US$13.8 million. This increase of US$13.8 million in the nine months of FY2018 was due to a 162% increase in commercialization revenue (US$1.6 million) from royalty income on sales of TEMCELL® Hs. Inj., an upfront payment of US$5.9 million (€5.0 million) received upon execution of our patent license agreement with TiGenix in December 2017, a future payment from TiGenix of US$5.9 million (€5.0 million), due by December 2018, was recognized, and an increase of US$0.5 million in sales milestones recognized on sales of TEMCELL® Hs. Inj.

- **Research and Development** expenses were US$48.4 million for the nine months of FY2018, compared with US$43.0 million for the nine months of FY2017, an increase of US$5.4 million (13%) as the Company invested in Tier 1 clinical programs.

- **Manufacturing** expenses were US$3.4 million for the nine months of FY2018, compared with US$10.9 million for the nine months of FY2017, a decrease of US$7.5 million (69%) 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$16.7 million for the nine months of FY2018, compared with US$15.9 million for the nine months of FY2017, an increase of US$0.8 million (5%) primarily due to increased legal activities and labor costs for non-cash share based payments partially offset by a decrease in corporate overhead expenses such as rent, IT costs and depreciation.

- **Finance Costs** of US$0.4 million in interest expenses were recognized in the nine months of FY2018 in relation to the Company's loan and security agreement entered into with Hercules in March 2018. No interest expense was recognized in the nine months of FY2017.

The overall decrease in loss after 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.

A non-cash income tax benefit of US$29.7 million was recognized in the nine months of FY2018 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period, primarily due to a revaluation of our deferred tax assets and liabilities recognized as a result of changes in tax rates. On December 22, 2017, the United States signed into law the Tax Cuts and Jobs Act (the Tax Act), which changed many aspects of United States corporate income taxation, including a reduction in the corporate income tax rate from 35% to 21%.

A non-cash income tax benefit of US$9.3 million was recognized in the nine months of FY2017 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was US$14.5 million, or 3.12 cents loss per share, for the nine months of FY2018, compared with US$49.6 million, or 12.75 cents loss per share, for the nine months of FY2017.

Conference Call Details

There will be a webcast today on the financial results beginning at 6:30 pm ET on Wednesday, May 30, 2018; 8:30 am Thursday, May 31, 2018 AEST.

The live webcast can be accessed via http://webcasting.brrmedia.com/broadcast/5b0b3e055f522f0d08dbbb1c

To access the call only, dial 1 855 881 1339 (U.S.), 1 800 558 698 (toll-free Australia) or +61 2 9007 3187 (outside of the U.S. and Australia). The conference identification code is 461736.

The archived webcast will be available on the Investor page of the Company's website – www.mesoblast.com

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.

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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017	Nine Months Ended March 31, 2018	Nine Months Ended March 31, 2017
Revenue	1,070	901	15,641	1,846
Research & development	(16,798)	(13,928)	(48,388)	(42,975)
Manufacturing commercialization	(1,709)	(3,830)	(3,387)	(10,915)
Management and administration	(6,033)	(5,521)	(16,688)	(15,859)
Fair value remeasurement of contingent consideration	(822)	9,117	7,880	7,778
Other operating income and expenses	152	384	1,243	1,168
Finance costs	(423)	—	(423)	—
Loss before income tax	**(24,563)**	**(12,877)**	**(44,122)**	**(58,957)**
Income tax benefit/(expense)	3,426	3,093	29,666	9,324
Loss attributable to the owners of Mesoblast Limited	**(21,137)**	**(9,784)**	**(14,456)**	**(49,633)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(4.47)	(2.43)	(3.12)	(12.75)
Diluted - losses per share	(4.47)	(2.43)	(3.12)	(12.75)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017	Nine Months Ended March 31, 2018	Nine Months Ended March 31, 2017
Loss for the year	**(21,137)**	**(9,784)**	**(14,456)**	**(49,633)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Changes in the fair value of available-for-sale financial assets	74	(86)	141	(55)
Exchange differences on translation of foreign operations	(69)	942	(569)	368
Other comprehensive (loss)/income for the period, net of tax	**5**	**856**	**(428)**	**313**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(21,132)**	**(8,928)**	**(14,884)**	**(49,320)**

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Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of March 31, 2018	As of June 30, 2017
Assets		
Current Assets		
Cash & cash equivalents	59,539	45,761
Trade & other receivables	12,074	3,743
Prepayments	14,456	14,105
Total Current Assets	**86,069**	**63,609**
Non-Current Assets		
Property, plant and equipment	1,263	1,814
Available-for-sale financial assets	2,138	1,997
Other non-current assets	3,386	1,916
Intangible assets	585,003	586,350
Total Non-Current Assets	**591,790**	**592,077**
Total Assets	**677,859**	**655,686**
Liabilities		
Current Liabilities		
Trade and other payables	20,475	21,805
Provisions	4,386	14,865
Total Current Liabilities	**24,861**	**36,670**
Non-Current Liabilities		
Deferred tax liability	21,100	49,293
Provisions	44,341	52,957
Borrowings	31,422	—
Total Non-Current Liabilities	**96,863**	**102,250**
Total Liabilities	**121,724**	**138,920**
Net Assets	**556,135**	**516,766**
Equity		
Issued Capital	879,482	830,425
Reserves	36,011	31,243
(Accumulated losses)/retained earnings	(359,358)	(344,902)
Total Equity	**556,135**	**516,766**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Nine months ended March 31, 2018	2017
Cash flows from operating activities		
Commercialization revenue received	2,529	1,012
Milestone payment received	6,125	—
Payments to suppliers and employees (inclusive of goods and services tax)	(63,719)	(73,443)
Interest received	266	395
Income taxes (paid)/refunded	(25)	—
Net cash (outflows) in operating activities	**(54,824)**	**(72,036)**
Cash flows from investing activities		
Payments for contingent consideration	(543)	—
Investment in fixed assets	(174)	(315)
Rental deposits received	—	453
Net cash (outflows)/inflows in investing activities	**(717)**	**138**
Cash flows from financing activities		
Net proceeds from borrowings	31,704	—
Payments of transaction costs from borrowings	(40)	—
Proceeds from issue of shares	40,566	61,784
Payments for share issue costs	(2,604)	(1,884)
Net cash inflows by financing activities	**69,626**	**59,900**
Net increase/(decrease) in cash and cash equivalents	14,085	(11,998)
Cash and cash equivalents at beginning of period	45,761	80,937
FX (losses)/gains on the translation of foreign bank accounts	(307)	183
Cash and cash equivalents at end of period	**59,539**	**69,122**

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