asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS FOURTH QUARTER AND FULL-YEAR 2018 FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS

Melbourne, Australia; August 30, 2018; and New York, USA, August 29, 2018: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported strong financial results and provided operational highlights for the fourth quarter and full-year ended June 30, 2018 (FY2018).

Key financial results for the 12 months ended June 30, 2018

- Revenues significantly increased to US$17.3 million in FY2018 compared with US$2.4 million in FY2017
- Commercialization revenues from sales of TEMCELL®[1] HS Inj. in Japan increased by 152%
- Significant reduction in loss after tax by US$41.5 million (54%) to US$35.3 million in FY2018 from US$76.8 million in FY2017
- Substantial reduction in operating cash outflows in FY2018 of US$20.5 million (21%) compared with FY2017
- Pro-forma cash on June 30, 2018 was US$116.8 million including:
  - US$37.8 million balance sheet cash
  - US$39.0 million from NovaQuest Capital Management through a strategic financing agreement in July 2018, and
  - US$40.0 million from Tasly Pharmaceutical Group through agreements entered into in July 2018, subject to filing with the State Administration of Foreign Exchange
- An additional US$50.0 million may be available under existing arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones.

Corporate highlights

Mesoblast entered into a strategic alliance with Tasly Pharmaceutical Group for the development, manufacture and commercialization of MPC-150-IM and MPC-25-IC in the treatment and prevention of chronic heart failure and heart attacks in China.

Mesoblast granted TiGenix NV (now fully owned by Takeda Pharmaceutical Co. Ltd) exclusive access to certain of its patents to support global commercialization of Alofisel® in the local treatment of fistulae. This product is the first allogeneic mesenchymal stem cell therapy to receive approval from the European Commission. As consideration, Mesoblast will receive up to €20 million in payments, as well as single digit royalties on net sales.

Mesoblast accessed non-dilutive capital for commercialization of MSC-100-IV (remestemcel-L) through credit facilities with Hercules Capital and NovaQuest.

New non-executive Directors Joseph R. Swedish and Shawn Cline Tomasello joined the Board of Directors, bringing substantial commercial and transactional healthcare expertise.

Operational highlights and anticipated upcoming milestones

MSC-100-IV (remestemcel-L) for pediatric steroid-refractory acute Graft Versus Host Disease (SR-aGVHD):

- The Phase 3 primary endpoint was successfully met
- The primary endpoint of Day 28 overall response rate to remestemcel-L treatment was 69%, a statistically significant increase compared to the protocol-defined historical control rate of 45% (p=0.0003)
- Day 100 survival results demonstrated 87% survival rate for Day 28 responders (33/38), and an overall survival rate of 75% (41/55)

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- These results were presented at the 2018 annual meeting of the International Society for Stem Cell Research
- The multi-infusion regimen of remestemcel-L was safe and well tolerated
- Day 180 survival results are expected shortly
- Based on discussions with the United States Food and Drug Administration (FDA), Mesoblast believes that successful results from the completed Phase 3 trial may provide sufficient clinical evidence to initiate filing of a marketing authorization for this product candidate in the United States.

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

- Upcoming 12 month database lock for Phase 2b trial in 159 patients with end-stage heart failure and a left ventricular assist device
- Full trial results to be presented at upcoming major cardiovascular conference
- Mesoblast is in active discussions with the FDA on the regulatory pathway under the granted Regenerative Medicine Advanced Therapy (RMAT) designation for MPC therapy in this indication granted in December 2017.

- Enrollment completion for the Phase 3 events-driven trial for Advanced Heart Failure Class II/III anticipated Q4 CY18
- Trial received a recommendation from the Independent Data Monitoring Committee to continue without modification after an evaluation of clinical safety data in the first 465 randomized patients
- Mesoblast plans to leverage results of this Phase 3 trial from complementary global trials performed by strategic partners.

MPC-06-ID for Chronic Low Back Pain:

- Enrollment was completed during FY2018 in Mesoblast's Phase 3 trial in patients with chronic low back pain who have failed conservative therapy
- A total of 404 patients across 48 sites are being followed for evaluation of treatment-related improvement in pain and function over two years.

Financial Results for the Three Months Ended June 30, 2018 (fourth quarter) (in U.S. Dollars)

Loss after tax was significantly reduced by US$6.3 million (23%) for the fourth quarter of FY2018, compared with the fourth quarter of FY2017 due to the items below:

- **Revenues** were US$1.7 million in the fourth quarter of FY2018, of which US$1.6 million was due to sales of TEMCELL by our licensee in Japan, JCR Pharmaceuticals Co. Ltd. Revenues increased by US$1.1 million (200%) compared with the fourth quarter of FY2017.

- **Research and Development** expenses were US$17.5 million for the fourth quarter of FY2018, compared with US$15.9 million for the fourth quarter of FY2017, an increase of US$1.6 million (10%) as the Company invested in Tier 1 clinical programs.

- **Manufacturing** expenses were US$2.1 million for the fourth quarter of FY2018, compared with US$1.2 million for the fourth quarter of FY2017, an increase of US$0.9 million (84%) primarily due to an increase in process validation activities for MSC-based manufacturing.

- **Management and Administration** expenses were US$5.2 million for the fourth quarter of FY2018, compared with US$7.1 million for the fourth quarter of FY2017, a decrease of US$1.9 million (27%) due to an overall decrease in corporate activities.

- **Finance Costs** of US$1.4 million in interest expenses were recognized in the fourth 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 fourth 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$1.0 million was recognized in the fourth 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$4.1 million in the fourth quarter of FY2017.

The net loss attributable to ordinary shareholders was US$20.8 million, or 4.39 cents loss per share, for the fourth quarter of FY2018, compared with US$27.2 million, or 6.34 cents loss per share, for the fourth quarter of FY2017.

At June 30, 2018, the Company had cash reserves of US$37.8 million. As of June 30, 2018, the Company recognized funds receivable from debt financing and unissued capital of US$39.0 million pursuant to a financing facility with NovaQuest. On July 10, 2018 the net proceeds from the financing facility of US$39.0 million were received and recognized in cash reserves. The Company will also receive US$40.0 million from Tasly on closing of the strategic alliance that the two companies announced in July 2018 for cardiovascular therapies in China. This transaction has been approved by the Tianjin Bureau of Ministry of Commerce and the Tianjin Bureau of National Development Reform Commission, and is subject to filing with the State Administration of Foreign Exchange.

Mesoblast retains an equity facility for up to A$120 million/US$90 million, to be used at its discretion over the next 12 months to provide additional funds as required.

Financial Results for the Year Ended June 30, 2018 (in U.S. Dollars)

Loss after tax was significantly reduced by US$41.5 million (54%) for FY2018, compared with FY2017.

The main items which reduced loss after income tax were:

- **Revenues** were US$17.3 million for FY2018, compared with US$2.4 million for FY2017, an increase of US$14.9 million. These revenues primarily consisted of US$11.8m from our patent license agreement with TiGenix (now fully owned by Takeda) in December 2017 and US$5.1 million in royalties and milestones from sales of TEMCELL by our licensee in Japan, JCR Pharmaceuticals Co. Ltd. Royalties from TEMCELL increased by 152% for FY2018 compared with FY2017.

- **Research and Development** expenses were US$65.9 million for FY2018, compared with US$58.9 million for FY2017, an increase of US$7.0 million (12%) as the Company invested in its phase 3 clinical programs.

- **Manufacturing** expenses were US$5.5 million for FY2018, compared with US$12.1 million for FY2017, a decrease of US$6.6 million (54%) 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$21.9 million for FY2018, compared with US$23.0 million for FY2017, a decrease of US$1.1 million (5%) primarily due to decreased legal activities and corporate overhead expenses such as rent, IT costs and depreciation. This decrease was partially offset by an increase in labor costs primarily for recruitment and short term incentives.

- **Finance Costs** of US$1.8 million in interest expenses were recognized in FY2018 in relation to the Company's loan and security agreement entered into with Hercules in March 2018. No interest expense was recognized in 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$30.7 million was recognized in 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$13.4 million was recognized in 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$35.3 million, or 7.58 cents loss per share, for FY2018, compared with US$76.8 million, or 19.25 cents loss per share, for FY2017.

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

Conference Call Details

There will be a webcast today on the financial results beginning at 6:00 pm EDT on Wednesday, August 29, 2018; 8:00 am Thursday, August 30, 2018 AEST.

The live webcast can be accessed via
http://webcasting.boardroom.media/broadcast/5b7512acb14eaa0d350808c4

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 471961.

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

About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO).
www.mesoblast.com

Forward-Looking Statements

This announcement 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 timing, progress and results of Mesoblast's preclinical and clinical studies; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; 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:

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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	(unaudited) Three Months Ended June 30, 2018	2017	(audited) Year Ended June 30, 2018	2017
Revenue	1,700	566	17,341	2,412
Research & development	(17,539)	(15,939)	(65,927)	(58,914)
Manufacturing commercialization	(2,121)	(1,150)	(5,508)	(12,065)
Management and administration	(5,219)	(7,148)	(21,907)	(23,007)
Fair value remeasurement of contingent consideration	2,661	(7,908)	10,541	(130)
Other operating income and expenses	69	321	1,312	1,489
Finance costs	(1,406)	—	(1,829)	—
Impairment of intangible assets	—	—	—	—
Loss before income tax	**(21,855)**	**(31,258)**	**(65,977)**	**(90,215)**
Income tax benefit/(expense)	1,021	4,076	30,687	13,400
Loss attributable to the owners of Mesoblast Limited	**(20,834)**	**(27,182)**	**(35,290)**	**(76,815)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(4.39)	(6.34)	(7.58)	(19.25)
Diluted - losses per share	(4.39)	(6.34)	(7.58)	(19.25)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	(unaudited) Three Months Ended June 30, 2018	2017	(audited) Year Ended June 30, 2018	2017
Loss for the year	**(20,834)**	**(27,182)**	**(35,290)**	**(76,815)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Changes in the fair value of available-for-sale financial assets	183	86	324	31
Exchange differences on translation of foreign operations	(334)	(52)	(903)	316
Other comprehensive (loss)/income for the period, net of tax	**(151)**	**34**	**(579)**	**347**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(20,985)**	**(27,148)**	**(35,869)**	**(76,468)**

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Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of June 30, 2018	2017
Assets		
Current Assets		
Cash & cash equivalents	37,763	45,761
Trade & other receivables	50,366	3,743
Prepayments	12,942	14,105
Total Current Assets	**101,071**	**63,609**
Non-Current Assets		
Property, plant and equipment	1,084	1,814
Available-for-sale financial assets	2,321	1,997
Other non-current assets	3,361	1,916
Intangible assets	584,606	586,350
Total Non-Current Assets	**591,372**	**592,077**
Total Assets	**692,443**	**655,686**
Liabilities		
Current Liabilities		
Trade and other payables	18,921	21,805
Provisions	5,082	14,865
Total Current Liabilities	**24,003**	**36,670**
Non-Current Liabilities		
Deferred tax liability	20,079	49,293
Provisions	42,956	52,957
Borrowings	59,397	—
Total Non-Current Liabilities	**122,432**	**102,250**
Total Liabilities	**146,435**	**138,920**
Net Assets	**546,008**	**516,766**
Equity		
Issued Capital	889,481	830,425
Reserves	36,719	31,243
(Accumulated losses)/retained earnings	(380,192)	(344,902)
Total Equity	**546,008**	**516,766**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Year ended June 30, 2018	2017
Cash flows from operating activities		
Commercialization revenue received	3,019	1,332
Milestone payment received	7,125	500
Research and development tax incentive received	—	2,813
Payments to suppliers and employees (inclusive of goods and services tax)	(84,682)	(100,598)
Interest received	367	483
Interest paid	(816)	—
Income taxes (paid)/refunded	(25)	(1)
Net cash (outflows) in operating activities	**(75,012)**	**(95,471)**
Cash flows from investing activities		
Payments for contingent consideration	(952)	—
Investment in fixed assets	(201)	(311)
Rental deposits received	—	453
Payments for investments	—	—
Payments for licenses	—	—
Net cash (outflows)/inflows in investing activities	**(1,153)**	**142**
Cash flows from financing activities		
Proceeds from borrowings	31,704	—
Payments of transaction costs from borrowings	(392)	—
Proceeds from issue of shares	40,566	61,932
Payments for share issue costs	(3,265)	(1,927)
Net cash inflows by financing activities	**68,613**	**60,005**
Net decrease in cash and cash equivalents	(7,552)	(35,324)
Cash and cash equivalents at beginning of period	45,761	80,937
FX (losses)/gains on the translation of foreign bank accounts	(446)	148
Cash and cash equivalents at end of period	**37,763**	**45,761**

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