asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS FIRST QUARTER ENDED SEPTEMBER 30, 2018 FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS

Melbourne, Australia, November 16, 2018 and New York, USA, November 15, 2018: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported strong financial results and provided operational highlights for the first quarter ended September 30, 2018.

Key financial results for the three months ended September 30, 2018 (first quarter FY2019)

- Significant increase in revenues to US$11.6 million in the first quarter FY2019, compared with US$1.2 million in the first quarter FY2018
- 66% increase in commercialization revenue from royalty income on sales of TEMCELL®[1] HS. Inj. for the quarter, compared with first quarter FY2018
- Reduction in operating cash outflows in first quarter FY2019 of US$0.8 million (4%) compared with first quarter FY2018
- Loss after tax increased by $12.5 million compared to the first quarter FY2018, $10.1 million of which is due to non-cash remeasurement of contingent consideration in the comparative quarter
- Pro-forma cash on September 30, 2018 was US$95.1 million including:
  - US$55.1 million balance sheet cash, and
  - US$40.0 million from Tasly Pharmaceutical Group (Tasly) received in October 2018 in relation to the strategic cardiovascular partnership in China announced in July 2018
- 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

- Results of a 159-patient randomized placebo-controlled Phase 2 trial, sponsored and conducted by United States National Institutes of Health (NIH), evaluating MPC-150-IM in the treatment of end-stage heart failure patients implanted with a left ventricular assist device (LVAD) were presented at the 2018 American Heart Association Scientific Sessions.
  - The trial succeeded in achieving the clinically meaningful outcome of reduction in gastrointestinal (GI) bleeding and related hospitalizations
  - Results confirm the previous pilot trial, which also demonstrated significant reduction in GI bleeding and related hospitalizations in MPC-150-IM treated LVAD patients
  - Pilot trial results formed the basis for the FDA Regenerative Medicine Advanced Therapy (RMAT) designation granted in December 2017
  - The RMAT designation under the 21st Century Cures Act aims to expedite the development of regenerative medicine therapies intended for the treatment of serious diseases and life-threatening conditions
  - Company intends to meet with the FDA in 1H CY2019 to provide full study data and discuss pathway to potential Biologics License Application (BLA) filing using reduction in GI bleeding and related hospitalizations as an approvable regulatory endpoint
  - While the trial did not meet the overall primary endpoint of temporary weaning, MPC-150-IM treatment did significantly improve weaning in the 44% of patients with chronic ischemic heart failure
  - LVAD patients with ischemic heart failure closely resemble the majority of patients enrolled in the ongoing Phase 3 trial of approximately 600 patients with moderate/ advanced heart failure

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- Mesoblast's Phase 3 trial of its product candidate remestemcel-L in children with steroid-refractory acute Graft Versus Host Disease (aGVHD) demonstrated strong survival outcomes through Day 180. Mesoblast is preparing for a pre-BLA meeting to initiate filing of a marketing authorization for this product candidate in the United States.

- Mesoblast expanded its partnership with JCR Pharmaceuticals Co. Ltd. (JCR) for the treatment of wound healing in epidermolysis bullosa (EB). Having been granted Orphan Regenerative Medical Product designation for EB in October, JCR now intends to seek a label extension for TEMCELL® in Japan for EB beyond its existing approval for the treatment of aGVHD.

- Mesoblast completed its transaction with Tasly to establish a strategic cardiovascular partnership in China. In addition to US$40 million received on closing the transaction, Mesoblast is eligible to receive up to US$25 million on product regulatory approval in China, double-digit escalating royalties on net product sales as well as six escalating milestone payments upon the achievement of certain product sales thresholds in China.

Operational Highlights and Anticipated Upcoming Milestones

MPC-150-IM for Moderate to Advanced Heart Failure:

- The ongoing Phase 3 trial received a recommendation in October 2018 from the unblinded Independent Data Monitoring Committee to continue without modification after an evaluation of clinical safety data in the first 526 randomized patients.

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

- Mesoblast will seek a pre-BLA meeting to initiate filing of a marketing authorization for remestemcel-L in the United States, where there are currently no approved therapies for aGVHD.

- An existing Fast Track designation from the FDA allows eligibility for priority review and a rolling BLA review process.

MPC-06-ID for Chronic Low Back Pain:

- Mesoblast's Phase 3 trial in patients with chronic low back pain who have failed conservative therapy completed enrollment in March 2018, with a total of 404 patients across 48 sites being followed out for evaluation of treatment-related improvement in pain and function.

Financial Results for the Three Months Ended September 30, 2018 (first quarter FY2019) (in U.S. Dollars)

- **Revenues** were US$11.6 million for the first quarter FY2019, compared with US$1.2 million for the first quarter FY2018, an increase of US$10.5 million. These revenues primarily consisted of:
  - US$1.5 million in royalties and milestones from sales of TEMCELL by our licensee in Japan, JCR Pharmaceuticals Co. Ltd. Royalties from TEMCELL increased by 66% for first quarter FY2019 compared with the first quarter FY2018
  - US$10.0 million milestone revenue in relation to establishing a strategic cardiovascular partnership with Tasly in China

- **Research and Development** expenses were US$18.5 million for the first quarter FY2019, compared with US$15.4 million for the first quarter FY2018, an increase of US$3.1 million (20%) as the Company invested in its Tier 1 clinical programs

- **Manufacturing** expenses were US$4.3 million for the first quarter FY2019, compared with US$0.9 million for the first quarter FY2018, an increase of US$3.4 million due to an increase in manufacturing activities in preparation for filing the Biologics License Application (BLA) for MSC-100-IV

- **Management and Administration** expenses were US$5.6 million for the first quarter FY2019, compared with US$5.0 million for the first quarter FY2018, an increase of US$0.6 million (12%) primarily due to increased legal and professional fees associated with establishing the strategic cardiovascular partnership with Tasly

- **Finance Costs** of US$2.6 million in interest expenses were recognized in first quarter FY2019 in relation to loan and security agreements entered into with Hercules Capital in March 2018 and NovaQuest Capital in June 2018. No interest expense was recognized in the first quarter FY2018

Additional components of loss after income tax also include 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$0.7 million was recognized in the first quarter FY2019 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period. 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%. In the first quarter FY2018 deferred tax assets in the United States were recognized at 35% compared with 21% in the first quarter FY2019.

A non-cash income tax benefit of US$2.9 million was recognized in first quarter FY2018 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$19.5 million, or 4.07 cents loss per share, for the first quarter FY2019, compared with US$7.0 million, or 1.58 cents loss per share, for the first quarter FY2018.

[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 4.30pm on Thursday, November 15, 2018 EST; 8:30 am on Friday, November 16, 2018 AEDT.

The live webcast can be accessed via
http://webcasting.boardroom.media/broadcast/5bcfb51cf6a4f554d0fe76af

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 667811.

The archived webcast will be available on the Investor page of the Company's website:
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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)	Three Months Ended September 30, 2018	2017
Revenue	11,637	1,174
Research & development	(18,489)	(15,368)
Manufacturing commercialization	(4,317)	(877)
Management and administration	(5,614)	(5,012)
Fair value remeasurement of contingent consideration	(622)	9,495
Other operating income and expenses	(151)	668
Finance costs	(2,653)	—
Loss before income tax	**(20,209)**	**(9,920)**
Income tax benefit/(expense)	711	2,898
Loss attributable to the owners of Mesoblast Limited	**(19,498)**	**(7,022)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(4.07)	(1.58)
Diluted - losses per share	(4.07)	(1.58)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2018	2017
Loss for the period	**(19,498)**	**(7,022)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Changes in the fair value of available-for-sale financial assets	87	20
Exchange differences on translation of foreign operations	(23)	(358)
Other comprehensive income/(loss) for the period, net of tax	**64**	**(338)**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(19,434)**	**(7,360)**

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Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of September 30, 2018	As of June 30, 2018
Assets		
Current Assets		
Cash & cash equivalents	55,143	37,763
Trade & other receivables	29,539	50,366
Prepayments	13,129	12,942
Total Current Assets	**97,811**	**101,071**
Non-Current Assets		
Property, plant and equipment	1,016	1,084
Available-for-sale financial assets	2,408	2,321
Other non-current assets	3,344	3,361
Intangible assets	584,210	584,606
Total Non-Current Assets	**590,978**	**591,372**
Total Assets	**688,789**	**692,443**
Liabilities		
Current Liabilities		
Trade and other payables	19,292	18,921
Provisions	8,101	5,082
Total Current Liabilities	**27,393**	**24,003**
Non-Current Liabilities		
Deferred tax liability	19,368	20,079
Deferred consideration	10,000	—
Provisions	43,270	42,956
Borrowings	61,159	59,397
Total Non-Current Liabilities	**133,797**	**122,432**
Total Liabilities	**161,190**	**146,435**
Net Assets	**527,599**	**546,008**
Equity		
Issued Capital	889,980	889,481
Reserves	37,309	36,719
(Accumulated losses)/retained earnings	(399,690)	(380,192)
Total Equity	**527,599**	**546,008**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three months ended September 30, 2018	2017
Cash flows from operating activities		
Commercialization revenue received	1,095	474
Milestone payment received	500	—
Research and development tax incentive received	1,654	—
Payments to suppliers and employees (inclusive of goods and services tax)	(22,039)	(20,892)
Interest received	136	63
Interest paid	(887)	—
Income taxes (paid)/refunded	(3)	(1)
Net cash (outflows) in operating activities	**(19,544)**	**(20,356)**
Cash flows from investing activities		
Investment in fixed assets	(39)	(83)
Payments for contingent consideration	—	(543)
Net cash (outflows)/inflows in investing activities	**(39)**	**(626)**
Cash flows from financing activities		
Proceeds from borrowings	28,950	—
Payments of transaction costs from borrowings	(1,534)	—
Proceeds from issue of shares	10,048	40,449
Payments for share issue costs	(358)	(2,001)
Net cash inflows by financing activities	**37,106**	**38,448**
Net decrease in cash and cash equivalents	17,523	17,466
Cash and cash equivalents at beginning of period	37,763	45,761
FX (losses)/gains on the translation of foreign bank accounts	(143)	(286)
Cash and cash equivalents at end of period	**55,143**	**62,941**

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