asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS FOR THE FIRST HALF ENDED DECEMBER 31, 2018

Strong cash reserves as Company prepares for potential US launch of remestemcel-L

Melbourne, Australia, February 21, 2019 and New York, USA, February 20, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported its financial results and operational highlights for the six months ended December 31, 2018. Pro-forma cash on hand at December 31, 2018 was US$92.0 million (A$130.0 million).

Chief Executive Dr Silviu Itescu said: "The highlights from the half year include completion of enrollment in our major cardiovascular Phase 3 trial, execution of our cardiovascular partnership in China, and continued revenue growth from product sales by our licensee in Japan for treatment of acute graft versus host disease (aGVHD). Our focus in the coming period is on obtaining FDA approval for and ensuring a successful commercial launch of remestemcel-L for aGVHD in the United States."

Corporate Highlights for the Six Months Ended December 31, 2018 (first half FY2019):

- After demonstrating strong survival benefits through Day 180, Mesoblast held two successful end-of-phase meetings with the FDA covering clinical and manufacturing aspects of the upcoming Biologics License Application (BLA) for remestemcel-L in the US for use in children with steroid-refractory aGVHD.
- The Company now has a meeting scheduled with the FDA in April 2019 and is on track to subsequently initiate a BLA filing for marketing authorization.
- Mesoblast's Phase 3 trial in chronic heart failure completed patient enrollment, with 566 patients randomized to receive Revascor or placebo. The study, conducted across 55 centers in North America, will complete when sufficient primary endpoint events have accrued, which is likely to be within 12 months.
- Mesoblast completed its transaction with Tasly Pharmaceutical Group (Tasly) to establish a strategic cardiovascular partnership in China, and received US$40 million on closing.
- Mesoblast and Tasly held their first Joint Steering Committee meeting, with a shared objective to initiate a clinical study in China using similar clinical endpoints and targeting a similar patient population as in Mesoblast's North American Phase 3 trial. Tasly and Mesoblast will leverage each other's clinical trial results to support their respective regulatory submissions.
- The National Institutes of Health (NIH) sponsored 159-patient trial of Revascor in end-stage heart failure patients with a left ventricular assist device (LVAD) achieved a 76% reduction in major gastrointestinal (GI) bleeding events and a 65% reduction in associated hospitalizations. Under the Regenerative Medicine Advanced Therapy (RMAT) designation for this indication, Mesoblast has received guidance from the FDA that reduction in GI bleeding and related hospitalizations is a clinically meaningful outcome that could support product registration.
- Mesoblast has expanded its partnership with Japan's 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®[1] HS. Inj. in Japan for EB beyond its existing approval for the treatment of aGVHD.
- Management has been expanded to build a commercial team to support the Company's launch plans for remestemcel-L and operational leadership to drive product life cycle management, commercial manufacturing and regulatory interactions.

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

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

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668

T +65 6570 0635
F +65 6570 0176

- The Board of Directors is undergoing a structured succession plan and has brought on two new US-based Directors with proven expertise in product commercial launches, reimbursement and health system economics.

Upcoming Milestones in Second Half FY2019:

- Mesoblast intends to initiate BLA filing for marketing authorization of remestemcel-L following its FDA meeting scheduled for April 2019.
- Mesoblast's partner Tasly is planning to meet with the National Medical Products Administration of China to discuss the regulatory approval pathway for Revascor in China.
- Mesoblast intends to meet with the FDA to discuss the pathway for approval of Revascor for the reduction in GI bleeding in patients with LVADs.
- All patients in Mesoblast's Phase 3 trial in MPC-06-ID for chronic lower back pain will complete their 12-month assessment for safety and efficacy.

Key Financial Highlights for First Half FY2019:

- Pro forma cash of US$92.0 million at December 31, 2018.
    - This includes US$15.0 million received in January 2019 from Hercules Capital, Inc. (Hercules) after having successfully achieved the clinical milestone of reduction in major GI bleeding events and related hospitalizations in the NIH trial of Revascor in end stage heart failure patients with LVADs;
    - Additional non-dilutive capital of US$35.0 million may be available under existing arrangements with Hercules and NovaQuest Capital Management, L.L.C. (NovaQuest), subject to certain milestones.
- 43% increase in royalty income on sales of TEMCELL for aGVHD in Japan.
- Stable revenue of US$13.5 million, compared with US$14.6 million in the first half of FY2018.
- Increased investment in commercial manufacturing of US$8.0 million in preparation for potential aGVHD approval.
- 50% reduction in net operating cash outflows in the first half of FY2019 to US$17.5 million.

Detailed Financial Results for the Six Months Ended December 31, 2018 (first half FY2019):

- **Revenues** were US$13.5 million for the first half FY2019, compared with US$14.6 million for the first half FY2018, a decrease of US$1.1 million primarily due to:
    - US$10.0 million milestone revenue recognized in the first half FY2019 in relation to establishing a partnership with Tasly in China, compared with US$11.8 million milestone revenue recognized in the first half FY2018 in relation to the patent license agreement with Takeda Pharmaceutical Company Limited.
    - US$3.2 million royalties and milestones revenue recognized in the first half FY2019 from sales of TEMCELL by our licensee in Japan, JCR, compared with US$2.6 million in the first half FY2018, an increase of US$0.6 million. Royalty income from TEMCELL increased by 43% for the first half FY2019.
- **Research and Development** expenses were US$34.0 million for the first half FY2019, compared with US$31.6 million for the first half FY2018, an increase of US$2.4 million (8%) as the Company invested in its lead clinical programs.

- **Manufacturing** expenses were US$9.7 million for the first half FY2019, compared with US$1.7 million for the first half FY2018, an increase of US$8.0 million due to an increase in commercial manufacturing in preparation for GVHD approval.

- **Management and Administration** expenses were US$10.7 million for the first half FY2019, compared with US$10.6 million for the first half FY2018, an increase of only US$0.1 million (1%).

- **Finance Costs** of US$5.1 million related to loan and security agreements entered into with Hercules in March 2018 and NovaQuest in June 2018. No interest expense was recognized in the first half FY2018.

Additional components of loss after income tax also include movements in other items which did not impact current cash reserves, such as income tax benefits, fair value remeasurement of contingent consideration, remeasurement of borrowing arrangements and foreign exchange movements within other operating income and expenses.

In the first half FY2019 the Company reported a US$44.1 million loss after tax compared to a profit after tax of US$6.7 million for the first half FY2018. The increase in the loss is primarily due to, in the current period, investment in commercial manufacturing of US$8.0 million in preparation for GVHD approval, and an increase of US$5.1 million in finance costs; and in comparison period of first half FY2018 the Company recognized a one-off non-cash income tax benefit of US$23.0 million due to a revaluation of tax liabilities given changes in tax rates and a non-cash US$8.7 million gain on contingent consideration for reduction of future payments to third parties. The net loss attributable to ordinary shareholders was 9.08 cents loss per share, for the first half FY2019, compared with 1.46 cents earnings per share, for the first half of 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 Wednesday, February 20 EST; 8:30am on Thursday, February 21, 2019 AEDT.

The live webcast can be accessed via
https://webcasting.boardroom.media/broadcast/5c6107137e5a7b7d6e8941e4

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 774100.

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

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

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

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668

T +65 6570 0635
F +65 6570 0176

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 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 December 31, 2018	Three Months Ended December 31, 2017	Six Months Ended December 31, 2018	Six Months Ended December 31, 2017
Revenue	1,870	13,397	13,507	14,571
Research & development	(15,488)	(16,222)	(33,975)	(31,590)
Manufacturing commercialization	(5,401)	(801)	(9,717)	(1,678)
Management and administration	(5,126)	(5,643)	(10,742)	(10,655)
Fair value remeasurement of contingent consideration	(11)	(793)	(634)	8,702
Other operating income and expenses	(827)	423	(978)	1,091
Finance costs	(2,486)	—	(5,139)	—
Loss before income tax	**(27,469)**	**(9,639)**	**(47,678)**	**(19,559)**
Income tax benefit	2,865	23,342	3,575	26,240
(Loss)/profit attributable to the owners of Mesoblast Limited	**(24,604)**	**13,703**	**(44,103)**	**6,681**
(Losses)/earnings per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - (losses)/earnings per share	(5.00)	2.91	(9.08)	1.46
Diluted - (losses)/earnings per share	(5.00)	2.91	(9.08)	1.46

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017	Six Months Ended December 31, 2018	Six Months Ended December 31, 2017
(Loss)/profit for the period	**(24,604)**	**13,703**	**(44,103)**	**6,681**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Changes in the fair value of financial assets	108	47	195	67
Exchange differences on translation of foreign operations	(160)	(385)	(183)	(500)
Other comprehensive (loss)/income for the period, net of tax	**(52)**	**(338)**	**12**	**(433)**
Total comprehensive (losses)/income attributable to the owners of Mesoblast Limited	**(24,656)**	**13,365**	**(44,091)**	**6,248**

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

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

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668

T +65 6570 0635
F +65 6570 0176

Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of December 31, 2018	As of June 30, 2018
Assets		
Current Assets		
Cash & cash equivalents	77,022	37,763
Trade & other receivables	3,934	50,366
Prepayments	16,845	12,942
Total Current Assets	**97,801**	**101,071**
Non-Current Assets		
Property, plant and equipment	871	1,084
Financial assets at fair value through other comprehensive income	2,516	2,321
Other non-current assets	3,330	3,361
Intangible assets	583,815	584,606
Total Non-Current Assets	**590,532**	**591,372**
Total Assets	**688,333**	**692,443**
Liabilities		
Current Liabilities		
Trade and other payables	25,120	18,921
Provisions	5,594	5,082
Borrowings	3,095	—
Total Current Liabilities	**33,809**	**24,003**
Non-Current Liabilities		
Deferred tax liability	16,504	20,079
Deferred consideration	10,000	—
Provisions	43,076	42,956
Borrowings	60,387	59,397
Total Non-Current Liabilities	**129,967**	**122,432**
Total Liabilities	**163,776**	**146,435**
Net Assets	**524,557**	**546,008**
Equity		
Issued Capital	909,235	889,481
Reserves	39,617	36,719
(Accumulated losses)/retained earnings	(424,295)	(380,192)
Total Equity	**524,557**	**546,008**

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

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

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668

T +65 6570 0635
F +65 6570 0176

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Six months ended December 31, 2018	2017
Cash flows from operating activities		
Commercialization revenue received	2,101	1,080
Milestone payment received	26,409	6,125
Research and development tax incentive received	1,654	—
Payments to suppliers and employees (inclusive of goods and services tax)	(46,186)	(42,593)
Interest received	293	192
Interest paid	(1,783)	—
Income taxes (paid)/refunded	(3)	(25)
Net cash (outflows) in operating activities	**(17,515)**	**(35,221)**
Cash flows from investing activities		
Investment in fixed assets	(112)	(137)
Payments for contingent consideration	—	(543)
Net cash (outflows) in investing activities	**(112)**	**(680)**
Cash flows from financing activities		
Proceeds from borrowings	28,950	—
Payments of transaction costs from borrowings	(1,546)	—
Proceeds from issue of shares	30,258	40,532
Payments for share issue costs	(607)	(2,603)
Net cash inflows by financing activities	**57,055**	**37,929**
Net increase in cash and cash equivalents	39,428	2,028
Cash and cash equivalents at beginning of period	37,763	45,761
FX (losses) on the translation of foreign bank accounts	(169)	(403)
Cash and cash equivalents at end of period	**77,022**	**47,386**

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

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

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668

T +65 6570 0635
F +65 6570 0176