asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS FOR THE PERIOD ENDED MARCH 31, 2019

Major corporate milestone achieved in initiating BLA filing with FDA for Mesoblast's cell therapy in the treatment of acute graft versus host disease

Melbourne, Australia, May 31, 2019 and New York, USA, May 30, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported its financial results and operational highlights for the nine months ended March 31, 2019. Financial results for the period are in line with expectations including the Company's cash position at March 31, 2019 of US$70.4 million (A$99.3 million).

Mesoblast Chief Executive Dr Silviu Itescu stated: "We achieved a significant corporate milestone by initiating our first BLA submission to the FDA. We will focus our efforts on launch activities in preparation for our first product roll-out in the United States, and on our supply chain to meet the projected market demand for this and our follow-on products."

Recent Corporate Highlights

- The United States Food and Drug Administration (FDA) has agreed to a rolling Biologics License Application (BLA) review of remestemcel-L for the treatment of steroid-refractory acute Graft Versus Host Disease (aGVHD) in children.
- Mesoblast has initiated the rolling submission of the BLA to the FDA, with filing of the first module. The rolling process will provide opportunity for ongoing communication, and during this process the Company expects it will be able to adequately address any substantial matters raised by the FDA.
- Mesoblast and the International Center for Health Outcomes and Innovation Research at the Icahn School of Medicine at Mount Sinai entered into a Memorandum of Understanding to conduct a confirmatory clinical trial using Revascor for reduction of gastrointestinal (GI) bleeding in end-stage heart failure patients implanted with a left ventricular assist device (LVAD).
- Mesoblast's Phase 3 trial in advanced heart failure has 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.
- Mesoblast's Phase 3 trial in chronic low back pain has completed enrollment with 404 patients randomized to receive MPC-06-ID or placebo. All assessable patients have now completed at least 12 months of safety and efficacy follow-up.
- Mesoblast extended its license with JCR Pharmaceuticals Co., Ltd. (JCR) in Japan for use of TEMCELL®[1] HS Inj. in patients with Epidermolysis Bullosa. JCR has now filed to extend marketing approval for this indication.
- The Board appointed Joseph R. Swedish as Chairman in April 2019. Mr Swedish brings deep healthcare expertise and a track record in healthcare resource allocation and reimbursement metrics, as the Company enters commercial stage.

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Key Financial Highlights for the Nine Months of FY2019:

- Cash reserves of US$70.4 million at March 31, 2019. Additional non-dilutive capital of US$35.0 million may be available under existing arrangements with Hercules Capital, Inc. (Hercules) and NovaQuest Capital Management, L.L.C. (NovaQuest), subject to certain milestones.
- 28% increase in royalty income on sales of TEMCELL for aGVHD in Japan.
- Stable revenue of US$14.7 million, compared with US$15.6 million in the nine months of FY2018.
- Increased investment in commercial manufacturing of US$9.5 million to support potential launch for aGVHD product.
- 29% reduction in net operating cash outflows in the nine months of FY2019 to US$38.7 million.

Upcoming Milestones

Key milestones anticipated for CY2019 include:

- Completion of BLA filing for remestemcel-L in the treatment of steroid refractory aGVHD in children.
- Phase 3 trial in advanced heart failure continues accrual of primary endpoints through to completion.
- Meet with FDA to discuss pathway for approval of Revascor for the reduction of GI bleeding in end-stage heart failure patients implanted with a LVAD.
- Mesoblast's partner Tasly plans to meet with the National Medical Products Administration of China to discuss the regulatory approval pathway for Revascor in China.
- Patient follow up continues through 24-month assessment of safety and efficacy in the Company's Phase 3 trial of MPC-06-ID for chronic lower back pain.

Detailed Financial Results for the Nine Months Ended March 31, 2019 (nine months of FY2019):

- **Revenues** were US$14.7 million for the nine months of FY2019, compared with US$15.6 million for the nine months of FY2018. Revenues comprised:
  - US$10.0 million milestone revenue recognized in the nine months of FY2019 in relation to establishing a partnership with Tasly in China, compared with US$11.8 million milestone revenue recognized in the nine months of FY2018 in relation to the patent license agreement with Takeda Pharmaceutical Company Limited.
  - US$4.3 million royalties and milestones revenue recognized in the nine months of FY2019 from sales of TEMCELL by our licensee in Japan, JCR, compared with US$3.6 million in the nine months of FY2018, an increase of US$0.7 million. Royalty income from TEMCELL increased by 28% for the nine months of FY2019.
- **Research and Development** expenses were US$48.4 million for the nine months of FY2019, stable when compared to the nine months of FY2018. For the third quarter, Research and Development expenses decreased by US$2.4m versus the comparative quarter in FY2018.
- **Manufacturing** expenses were US$12.9 million for the nine months of FY2019, compared with US$3.4 million for the nine months of FY2018. This reflects commercial manufacturing investment to support potential launch for aGVHD product.
- **Management and Administration** expenses were US$16.0 million for the nine months of FY2019, a decrease of US$0.7 million on the comparative period of FY2018.

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- **Finance Costs** were US$7.9 million for the nine months of FY2019, compared with US$0.4 million for the nine months of FY2018, primarily due to expenses in relation to loan and security agreements entered into with Hercules in March 2018 and NovaQuest in June 2018.

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 nine months of FY2019, the net loss attributable to ordinary shareholders was 14.02 cents per share for the nine months of FY2019, compared with a loss per share of 3.12 cents for the nine months of FY2018. There was an after tax loss of US$69.1 million compared to $14.5 million for the nine months of FY2018. The increase in the loss is primarily due to commercial manufacturing investment of US$9.5 million to support potential launch for aGVHD product, and an increase of US$7.5 million in finance costs. In the comparative period of 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$7.9 million gain on remeasurement of contingent consideration for reduction of future payments to third parties.

[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 6.30pm on Thursday May 30, 2019 EDT; 8:30am on Friday May 31, 2019 AEST.

The live webcast can be accessed via
https://webcasting.boardroom.media/broadcast/5ce635514b5ab5633996c030

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 10000574.

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 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

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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, 2019	Three Months Ended March 31, 2018	Nine Months Ended March 31, 2019	Nine Months Ended March 31, 2018
Revenue	1,249	1,070	14,755	15,641
Research & development	(14,407)	(16,798)	(48,380)	(48,388)
Manufacturing commercialization	(3,193)	(1,709)	(12,910)	(3,387)
Management and administration	(5,256)	(6,033)	(15,998)	(16,688)
Fair value remeasurement of contingent consideration	(2,718)	(822)	(3,352)	7,880
Other operating income and expenses	(82)	152	(1,060)	1,243
Finance costs	(2,768)	(423)	(7,906)	(423)
Loss before income tax	**(27,175)**	**(24,563)**	**(74,851)**	**(44,122)**
Income tax benefit	2,205	3,426	5,778	29,666
Loss attributable to the owners of Mesoblast Limited	**(24,970)**	**(21,137)**	**(69,073)**	**(14,456)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(5.00)	(4.47)	(14.02)	(3.12)
Diluted - losses per share	(5.00)	(4.47)	(14.02)	(3.12)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018	Nine Months Ended March 31, 2019	Nine Months Ended March 31, 2018
Loss for the period	**(24,970)**	**(21,137)**	**(69,073)**	**(14,456)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Changes in the fair value of financial assets	85	74	280	141
Exchange differences on translation of foreign operations	79	(69)	(104)	(569)
Other comprehensive (loss)/income for the period, net of tax	**164**	**5**	**176**	**(428)**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(24,806)**	**(21,132)**	**(68,897)**	**(14,884)**

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Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of March 31, 2019	As of June 30, 2018
Assets		
Current Assets		
Cash & cash equivalents	70,385	37,763
Trade & other receivables	3,508	50,366
Prepayments	11,634	12,942
Total Current Assets	**85,527**	**101,071**
Non-Current Assets		
Property, plant and equipment	825	1,084
Financial assets at fair value through other comprehensive income	2,601	2,321
Other non-current assets	3,331	3,361
Intangible assets	583,421	584,606
Total Non-Current Assets	**590,178**	**591,372**
Total Assets	**675,705**	**692,443**
Liabilities		
Current Liabilities		
Trade and other payables	18,551	18,921
Provisions	6,592	5,082
Borrowings	9,359	—
Deferred consideration	10,000	—
Total Current Liabilities	**44,502**	**24,003**
Non-Current Liabilities		
Deferred tax liability	14,301	20,079
Provisions	45,742	42,956
Borrowings	70,218	59,397
Total Non-Current Liabilities	**130,261**	**122,432**
Total Liabilities	**174,763**	**146,435**
Net Assets	**500,942**	**546,008**
Equity		
Issued Capital	910,405	889,481
Reserves	39,802	36,719
(Accumulated losses)/retained earnings	(449,265)	(380,192)
Total Equity	**500,942**	**546,008**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Nine months ended March 31, 2019	2018
Cash flows from operating activities		
Commercialization revenue received	3,321	2,529
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)	(67,672)	(63,719)
Interest received	493	266
Interest paid	(2,906)	—
Income taxes (paid)	(3)	(25)
Net cash (outflows) in operating activities	**(38,704)**	**(54,824)**
Cash flows from investing activities		
Investment in fixed assets	(202)	(174)
Payments for contingent consideration	—	(543)
Net cash (outflows) in investing activities	**(202)**	**(717)**
Cash flows from financing activities		
Proceeds from borrowings	43,572	31,704
Payments of transaction costs from borrowings	(1,582)	(40)
Proceeds from issue of shares	30,258	40,566
Payments for share issue costs	(607)	(2,604)
Net cash inflows by financing activities	**71,641**	**69,626**
Net increase in cash and cash equivalents	32,735	14,085
Cash and cash equivalents at beginning of period	37,763	45,761
FX (losses) on the translation of foreign bank accounts	(113)	(307)
Cash and cash equivalents at end of period	**70,385**	**59,539**

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