asx announcement

MESOBLAST REPORTS FINANCIAL RESULTS AND CORPORATE HIGHLIGHTS FOR FIRST HALF ENDED DECEMBER 31, 2019

Melbourne, Australia, February 27, 2020 and New York, USA, February 26, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported financial, corporate and operational highlights for the half year ended December 31, 2019.

Mesoblast Chief Executive Dr Silviu Itescu stated: "We are very pleased with the substantial progress made by the Company as we seek US marketing approval for our lead product candidate RYONCIL™ (remestemcel-L) in the treatment of steroid-refractory acute graft versus host disease in children. The continued growth in revenues of TEMCELL in Japan is an important indicator for the potential of RYONCIL in the US market. Mesoblast has established a US commercial team to bring RYONCIL to market and we are preparing to launch this product in 2020, if approved."

Financial Highlights for the First Half FY2020 Compared with First Half FY2019:

- 43% increase in revenues to US$19.2 million, compared with US$13.5 million, comprising:
  - 73% growth in revenues to US$3.8 million from sales of TEMCELL HS Inj.®[1] by Mesoblast's licensee for steroid-refractory acute graft versus host disease (SR-aGVHD) in Japan, compared with US$2.2 million.
  - 36% increase in milestone revenues to US$15.0 million from strategic partnerships compared to US$11.0 million.
- 32% reduction in loss after tax (US$30.1 million compared with US$44.1 million) driven by:
  - 43% increase in total revenues.
  - 22% decrease in research and development spend (US$26.5 million compared with US$33.9 million).
- At December 31, 2019, cash on hand was US$81.3 million (A$116.1 million). Over the next 12 months, Mesoblast may have access to an additional US$62.5 million through existing financing facilities and strategic partnerships.

Operational and Corporate Highlights for the First Half FY2020:

- Mesoblast has filed a Biologics License Application (BLA) with the United States Food and Drug Administration (US FDA) to seek approval of remestemcel-L[2] for SR-aGVHD in children under the brand name RYONCIL[3].
- The continued growth in revenues from sales of TEMCELL in Japan informs on the potential US market and projected uptake of RYONCIL.
- Mesoblast has established a US commercial team for potential launch of its first allogeneic cellular product candidate RYONCIL for SR-aGVHD in children.
- An agreement was entered into with Lonza for the commercial manufacture of RYONCIL to facilitate inventory build ahead of the planned US market launch and for commercial supply to meet Mesoblast's long-term market projections.
- The Company has put in place a lifecycle extension strategy to generate evidence-based clinical outcomes to leverage the experience of bringing RYONCIL to market and to maximize the value of remestemcel-L in

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other pediatric and adult rare diseases that have short development timelines and do not require large distribution channels.

- The Phase 3 trial of REVASCOR® for advanced chronic heart failure surpassed the number of primary endpoint events required for trial completion.

- For MPC-06-ID for the treatment of chronic low back pain due to degenerative disc disease, Mesoblast entered into a strategic partnership with Grünenthal GmbH for Europe and Latin America.

- For these and additional product candidates that require large distribution channels, Mesoblast will enter into further global and/or regional strategic partnerships.[4]

Major Operational Milestones for the Next 12 Months

Remestemcel-L for SR-aGVHD and Other Rare Diseases

- Updates on Priority Review and Prescription Drug User Fee Act (PDUFA) date for RYONCIL for SR-aGVHD in children

- If approved, US launch of RYONCIL planned for 2020

- Expand investigator-initiated clinical trials for chronic GVHD and other indications

REVASCOR for Advanced and End Stage Heart Failure

- Data readout for advanced chronic heart failure Phase 3 trial planned for mid-2020

- Initiate confirmatory trial in end-stage heart failure

MPC-06-ID for Chronic Low Back Pain

- Data readout for Phase 3 trial planned for mid-2020

- Obtain clearance from European regulatory authorities to begin European Phase 3 trial

Lead Program Updates

Remestemcel-L for Pediatric and Adult Rare Diseases

RYONCIL for Steroid-refractory Acute GVHD in Children

- The Company has requested Priority Review of the BLA for RYONCIL by the FDA under the product candidate's existing Fast Track designation. If approved, this product is expected to be launched in the US in 2020.

- Clinical efficacy and safety data in the BLA for this product included analyses of 309 children with SR-aGVHD who have received remestemcel-L across three separate studies. In addition, Mesoblast provided new data in control pediatric subjects from the contemporaneous database of the Mount Sinai Acute GVHD International Consortium (MAGIC) to provide an unbiased and independent estimate of response rates and outcomes in matched pediatric control patients treated with institutional standard of care.

- Aggregated results from the 309 children who received RYONCIL for SR-aGVHD were presented to the annual meeting of the American Society for Transplantation Cellular Therapy and the Center for International Blood & Bone Marrow Transplant Research (TCT), held in February. The data indicated consistent safety and efficacy outcomes of RYONCIL as first-line treatment or salvage therapy, including in patients with the most severe forms of aGVHD.

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- Mesoblast's agreement with Lonza for commercial product manufacture is in line with the corporate strategy to facilitate appropriate inventory build ahead of the planned launch of RYONCIL. The agreement provides for Lonza to expand its Singapore cGMP facilities if required to meet long-term growth and capacity needs for the product. Additionally, it anticipates introduction of new technologies and process improvements which are expected to result in significant increases in yields and efficiencies.

Remestemcel-L for Steroid-refractory Chronic GVHD

- An investigator-initiated expanded access protocol using remestemcel-L for steroid-refractory chronic GVHD (chronic GVHD) resulted in clinically meaningful outcomes in all three treated patients, two children and one adult, within 28 days after two infusions.

- Based on these outcomes, the investigator-initiated collaboration will be expanded to evaluate remestemcel-L in a pivotal trial for chronic GVHD.

- Chronic GVHD occurs in 30-70% of recipients of an allogeneic bone marrow transplant. The prevalence of chronic GVHD in the US is over 14,000 patients, with an estimated annual patient medical cost of approximately US$300,000.

REVASCOR for Advanced and End-stage Heart Failure

- After surpassing the number of primary endpoints required for the completion of the Phase 3 trial of REVASCOR for advanced chronic heart failure, this cardiovascular-outcomes trial in 566 patients initiated final study visits for all surviving patients. A data readout of this Phase 3 trial is planned for mid-2020.

- The independent Data Monitoring Committee overseeing the Phase 3 trial held its 10th and final scheduled meeting and recommended that the trial continue as planned. The DMC reviewed available data from the 566 randomized patients, including components of the trial's primary and secondary endpoints, and all safety data.

- The Phase 3 trial results will be considered pivotal to support regulatory approval in the US, as well as in China through a partnership with Tasly Pharmaceuticals to develop and commercialize the product for advanced chronic heart failure.

- The American Heart Association journal *Circulation Research* published a Special Article highlighting the important potential clinical benefits of REVASCOR in patients with advanced chronic heart failure, stating that there is a biologic rationale for the use of this product in targeting cardiac inflammation in order to improve heart failure outcomes.

- Mesoblast and the International Center for Health Outcomes Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai in New York have agreed on a protocol for a confirmatory Phase 3 trial of REVASCOR in the treatment of patients with end-stage heart failure and a left ventricular assist device (LVAD), in line with FDA guidance. This product is being developed for these patients under existing FDA Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug Designations.

MPC-06-ID for Chronic Low Back Pain

- The Phase 3 trial of MPC-06-ID in 404 patients with chronic low back pain due to degenerative disc disease has a primary composite endpoint of improvement in pain and function through 24 months. Final study visits for all evaluable patients have been initiated, with a data readout planned for mid-2020.

- Grünenthal and Mesoblast have agreed on an overall development plan for the product to meet European regulatory requirements. As part of this plan, the companies are collaborating on the study design for a confirmatory Phase 3 trial in Europe, with the results of the two Phase 3 trials expected to support both FDA and European Medicines Agency regulatory approvals for MPC-06-ID in chronic low back pain due to degenerative disc disease.

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- Under the partnership with Grünenthal, Mesoblast may receive up to US$150 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments. These payments include commitments up to US$45 million within the first year. Cumulative milestone payments could exceed US$1 billion depending on the final outcome of Phase 3 studies and patient adoption. Mesoblast will also receive tiered double-digit royalties on product sales.

Financial Results for the Six Months Ended December 31, 2019 (First Half FY2020):

Loss after tax reduced by US$14.0 million to US$30.1 million for the first half FY2020 compared to US$44.1 million for the first half FY2019 as detailed below:

- **Revenues** increased US$5.7 million to US$19.2 million for the first half FY2020, compared to US$13.5 million for the first half FY2019.
    - Milestone revenue increased by US$4.0 million due to the up-front milestone payment of US$15.0 million for the strategic partnership with Grünenthal GmbH in the first half of FY2020. In the first half of FY2019 we recognized US$10.0 million of milestone revenue in relation to establishing a partnership with Tasly in China and US$1.0 million of cumulative sales milestones for sales of TEMCELL in Japan.
    - Royalty revenue on sales of TEMCELL in Japan increased US$1.6 million (73%) to US$3.8 million for the first half FY2020 compared with US$2.2 million for the first half FY2019.
- **Research and Development** expenses decreased by US$7.4 million to US$26.5 million for the first half FY2020, compared to US$33.9 million for the first half FY2019. This US$7.4 million decrease was due to a reduction in third party costs for our Phase 3 clinical trials as enrolment is now complete and activities are decreasing.
- **Manufacturing** expenses decreased by US$1.9 million to US$7.8 million for the first half FY2020, compared to US$9.7 million for the first half FY2019 due to a reduction in manufacturing activities related to filing the Biologics License Application (BLA) for RYONCIL offset by increased expenditure on pre-launch inventory for the potential launch of this product.
- **Management and Administration** expenses increased US$1.5 million to US$12.2 million for the first half FY2020, compared with US$10.7 million for the first half FY2019.
- **Finance Costs** for our borrowing arrangements with Hercules and NovaQuest were US$6.4 million for the first half FY2020, compared to US$5.1 million for the first half FY2019, an increase of US$1.3 million.
- **Income tax benefit** increased by US$0.6 million to US$4.2 million in the first half FY2020, compared with US$3.6 million in the first half FY2019 in relation to deferred tax liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was 5.82 US cents per share for the first half FY2020, compared with 9.08 US cents per share for the first half FY2019.

Financial Results for the Three Months Ended December 31, 2019 (second quarter FY2020):

Loss after tax of US$24.6 million remained consistent for the second quarter FY2020 compared with the second quarter FY2019 as detailed below:

- **Revenues** increased US$0.3 million to US$2.2 million for the second quarter FY2020, compared to US$1.9 million for the second quarter FY2019.
    - US$2.0 million royalties revenue recognized in the second quarter FY2020 from sales of TEMCELL in Japan, compared with US$1.7 million royalties and milestones revenue recognized in the second quarter of FY2019, an increase of US$0.3 million. Royalty income from TEMCELL increased by 61% for the second quarter of FY2020.

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- **Research and Development** expenses decreased by US$1.3 million to US$14.2 million for the second quarter FY2020, compared to US$15.5 million for the second quarter FY2019. This US$1.3 million decrease was due to a reduction in third party costs for our Phase 3 clinical trials as enrolment is now complete and activities are decreasing.

- **Manufacturing** expenses decreased by US$0.3 million to US$5.1 million for the second quarter FY2020, compared to US$5.4 million for the second quarter FY2019 due to a reduction in manufacturing activities related to filing the Biologics License Application (BLA) for RYONCIL offset by increased expenditure on pre-launch inventory for the potential launch of this product.

- **Management and Administration** expenses increased US$1.6 million to US$6.7 million for the second quarter FY2020, compared with US$5.1 million for the second quarter FY2019.

- **Finance Costs** for our borrowing arrangements with Hercules and NovaQuest were US$3.0 million for the second quarter FY2020, compared to US$2.5 million for the second quarter FY2019, an increase of US$0.5 million.

- **Income tax benefit** decreased by US$0.6 million to US$2.3 million in the second quarter FY2020, compared with US$2.9 million in the second quarter FY2019 in relation to deferred tax liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was 4.60 US cents per share for the second quarter FY2020, compared with 5.00 US cents per share for the second quarter FY2019.

Webcast

There will be a webcast today on the financial results beginning at 8.30am on Thursday February 27 AEDT; 4.30pm Wednesday, February 26, 2020 EST.

The live webcast can be accessed via
https://webcasting.boardroom.media/broadcast/5e4cd45be3e4a00857dbf7d4

To access the call only, dial 1 855 881 1339 (US), 1800 870 643 or 1800 809 971 (Australia) or +61 2 9007 3187 (outside of the US and Australia). The conference identification code is 10004384.

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

References

1. TEMCELL HS. Inj.® is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. United States Adopted Name (USAN) assigned to Mesoblast's *ex vivo* cultured allogeneic human mesenchymal stem cells.
3. RYONCIL has been accepted by the FDA as the brand name for Mesoblast's remestemcel-L product.
4. Mesoblast does not make any representation or give any assurance that such partnering transactions will be concluded.

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 mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Mesoblast's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast has filed a Biologics License Application to the United States Food and Drug Administration (FDA) to seek approval of its product candidate RYONCIL™ (remestemcel-L) for steroid-refractory acute graft versus host disease (acute GvHD). Remestemcel-L is also being developed for other rare diseases. Mesoblast is completing Phase 3 trials for its product candidates for advanced heart failure and chronic low back pain. If approved,

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RYONCIL is expected to be launched in the United States in 2020 for pediatric steroid-refractory acute GVHD. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

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.

Release authorized by the Chief Executive, as approved by the Board of Directors.

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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended December 31, 2019	Three Months Ended December 31, 2018	Six Months Ended December 31, 2019	Six Months Ended December 31, 2018
Revenue	2,206	1,870	19,254	13,507
Research & development	(14,154)	(15,488)	(26,543)	(33,975)
Manufacturing commercialization	(5,145)	(5,401)	(7,843)	(9,717)
Management and administration	(6,766)	(5,126)	(12,230)	(10,742)
Fair value remeasurement of contingent consideration	(595)	(11)	(882)	(634)
Other operating income and expenses	583	(827)	414	(978)
Finance costs	(2,982)	(2,486)	(6,439)	(5,139)
Loss before income tax	**(26,853)**	**(27,469)**	**(34,269)**	**(47,678)**
Income tax benefit	2,269	2,865	4,202	3,575
Loss attributable to the owners of Mesoblast Limited	**(24,584)**	**(24,604)**	**(30,067)**	**(44,103)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(4.60)	(5.00)	(5.82)	(9.08)
Diluted - losses per share	(4.60)	(5.00)	(5.82)	(9.08)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended December 31, 2019	Three Months Ended December 31, 2018	Six Months Ended December 31, 2019	Six Months Ended December 31, 2018
Loss for the period	**(24,584)**	**(24,604)**	**(30,067)**	**(44,103)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Financial assets at fair value through other comprehensive income	(280)	108	(645)	195
Exchange differences on translation of foreign operations	287	(160)	(45)	(183)
Other comprehensive income/(loss) for the period, net of tax	**7**	**(52)**	**(690)**	**12**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(24,577)**	**(24,656)**	**(30,757)**	**(44,091)**

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of December 31, 2019	As of June 30, 2019
Assets		
Current Assets		
Cash & cash equivalents	81,348	50,426
Trade & other receivables	3,091	4,060
Prepayments	8,868	8,036
Total Current Assets	**93,307**	**62,522**
Non-Current Assets		
Property, plant and equipment	1,554	826
Right-of-use assets	8,042	—
Financial assets at fair value through other comprehensive income	1,672	2,317
Other non-current assets	3,324	3,324
Intangible assets	582,338	583,126
Total Non-Current Assets	**596,930**	**589,593**
Total Assets	**690,237**	**652,115**
Liabilities		
Current Liabilities		
Trade and other payables	19,241	13,060
Provisions	26,097	7,264
Borrowings	18,928	14,007
Lease liabilities	2,691	—
Deferred consideration	10,000	10,000
Total Current Liabilities	**76,957**	**44,331**
Non-Current Liabilities		
Deferred tax liability	6,922	11,124
Provisions	30,375	48,329
Borrowings	65,996	67,279
Lease liabilities	6,683	—
Deferred consideration	2,500	—
Total Non-Current Liabilities	**112,476**	**126,732**
Total Liabilities	**189,433**	**171,063**
Net Assets	**500,804**	**481,052**
Equity		
Issued Capital	959,635	910,405
Reserves	42,054	40,638
(Accumulated losses)/retained earnings	(500,885)	(469,991)
Total Equity	**500,804**	**481,052**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Six months ended December 31, 2019	2018
Cash flows from operating activities		
Commercialization revenue received	3,610	2,101
Upfront and milestone payments received	17,500	26,409
Research and development tax incentive received	1,499	1,654
Payments to suppliers and employees (inclusive of goods and services tax)	(37,119)	(46,186)
Interest received	413	293
Interest and other costs of finance paid	(2,788)	(1,783)
Income taxes (paid)/refunded	(3)	(3)
Net cash (outflows) in operating activities	**(16,888)**	**(17,515)**
Cash flows from investing activities		
Investment in fixed assets	(612)	(112)
Payments for licenses	(100)	—
Net cash (outflows) in investing activities	**(712)**	**(112)**
Cash flows from financing activities		
Proceeds from borrowings	—	28,950
Payments of transaction costs from borrowings	—	(1,546)
Proceeds from issue of shares	51,053	30,258
Payments for share issue costs	(2,164)	(607)
Payment of lease liabilities	(695)	—
Net cash inflows by financing activities	**48,194**	**57,055**
Net increase in cash and cash equivalents	30,594	39,428
Cash and cash equivalents at beginning of period	50,426	37,763
FX gains/(losses) on the translation of foreign bank accounts	328	(169)
Cash and cash equivalents at end of period	**81,348**	**77,022**

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