

OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR THE PERIOD ENDED MARCH 31, 2021

Melbourne, Australia; June 3 and New York, USA; June 2, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported operational highlights and financial results for the period ended March 31, 2021.

"We are pleased with the recent clinical outcomes regarding our lead product candidate remestemcel-L and continue to progress our regulatory discussions with the aim of achieving approval. Our focus and top priority remains on successfully bringing remestemcel-L to children with the devastating complication of steroid-refractory acute graft versus host disease and adults fighting COVID-19 acute respiratory distress syndrome," said Silviu Itescu, Chief Executive of Mesoblast.

Operational Highlights

Remestemcel-L in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children:

- Mesoblast continues to be in discussion with the United States Food & Drug Administration (FDA) through a well-established regulatory process that may include a resubmission with a six month review with the aim of achieving approval of remestemcel-L in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children
- As part of this process, Mesoblast recently met with the FDA's Center for Biologics Evaluation and Research (CBER). Following CBER's recommendation after this meeting, Mesoblast as a next step will discuss with CBER's review team at the Office of Tissue and Advanced Therapies (OTAT) our approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assay validation

Remestemcel-L in the treatment of COVID-19 ARDS in adults:

- Results from the randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) indicated that in the pre-specified population under 65 years old (n=123), those who received remestemcel-L had a significantly reduced mortality through to 60 days. The trial had been halted after the third interim analysis and 222 enrolled patients since the 30-day primary endpoint would not be attained.
- In patients under 65 years, the benefit was further increased when remestemcel-L was used with dexamethasone as part of standard of care
- The trial also indicated that the mortality reduction by remestemcel-L in those under 65 years was accompanied by increased days alive off mechanical ventilation and reduced days in hospital

Rexlemestrocel-L in the treatment of chronic low back pain:

- Results from the trial of rexlemestrocel-L (MPC-06-ID) in 404 patients with chronic low back pain (CLBP) due to degenerative disc disease (DDD) indicated that a single injection of rexlemestrocel-L + hyaluronic acid (HA) carrier may provide at least two years of pain reduction, with opioid sparing activity in patients using opioids at baseline
- Significant and durable reductions in CLBP through 24 months were seen across the entire evaluable study population, and greatest pain reduction was observed in the pre-specified population with CLBP of shorter duration than the study median of 68 months
- The results indicate that treatment benefit may be greatest when inflammation is high and before irreversible fibrosis has occurred in the intervertebral disc

Financial Highlights

- Sales of TEMCELL® HS Inj.¹ in Japan for the treatment of aGVHD continue to recover from the effects of the temporary shutdown in production during mid-2020 which was undertaken in order to increase capacity to meet growing demand for the product
- Revenues from TEMCELL® royalties for the quarter ended March 31, 2021 were US\$1.9 million compared to US\$2.0 million in the quarter ended March 31, 2020
- Successful completion of US\$110 million private placement, with cash balance of US\$158.3 million at March 31, 2021
- Private placement was led by US investor group SurgCenter Development, one of the largest private operators of ambulatory surgical centres in the US specializing in spine, orthopaedic and total joint replacement
- Mesoblast entered into a contractual amendment with Hercules to extend the interest-only period of its debt facility through to at least October 2021

Key initiatives and Upcoming Milestones for the Next Two Quarters

Remestemcel-L

- In the treatment of steroid-refractory acute graft versus host disease (SR-GVHD) in children, Mesoblast plans to discuss with CBER's review team at the OTAT our approach to address certain outstanding CMC items, including potency assay validation
- In the regulatory pathway for remestemcel-L in patients with COVID-19 ARDS, Mesoblast intends to meet with FDA to discuss potential next steps based on the observed reduction in mortality in patients under 65 years in the recent trial
- The license and collaboration agreement between Mesoblast and Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the development of the treatment of ARDS, remains subject to certain closing conditions, including time during this period to analyze the results from the COVID-19 ARDS trial

Rexlemestrocel-L

- Mesoblast intends to meet with FDA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic discogenic lower back pain based on the observed durable reduction in pain and opioid sparing activity in the CLBP Phase 3 trial
- Mesoblast intends to meet with FDA to discuss potential next steps in the regulatory pathway for rexlemestrocel-L in patients with chronic heart failure based on the observed reduction in mortality and morbidity in the chronic heart failure Phase 3 trial

Remestemcel-L

Steroid-Refractory Acute Graft Versus Host Disease

Mesoblast continues to be in discussion with the United States Food & Drug Administration (FDA) through a well-established regulatory process that may include a resubmission with a six month review with the aim of achieving approval of remestemcel-L in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children.

As part of this process, Mesoblast recently met with the FDA's Center for Biologics Evaluation and Research (CBER). Following CBER's recommendation after this meeting, Mesoblast as a next step will discuss with CBER's review team at the Office of Tissue and Advanced Therapies (OTAT) our approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assay validation.

Acute Respiratory Distress Syndrome due to COVID-19

Mesoblast recently announced top-line 60-day outcomes from the randomized, placebo-controlled trial of remestemcel-L in 222 ventilator-dependent COVID-19 patients with moderate/severe ARDS which had been halted after the third interim analysis since the 30-day primary endpoint would not be

attained. Remestemcel-L reduced mortality through day 60 by 46% in the pre-specified group below age 65, but not in patients 65 or older. Remestemcel-L reduced mortality by 75% and increased days alive off mechanical ventilation in patients under age 65 when combined with dexamethasone, in comparison with controls on dexamethasone.

Reduction in mortality in mechanically ventilated patients under 65 years old remains a critical unmet need since as many as 72% of currently hospitalized patients across the US with COVID-19 are in this age category.² This is similar to other causes of viral ARDS such as influenza where 70-80% of patients in intensive care units are under 65.^{3,4} The trial enrolled 222 mechanically ventilated COVID-19 patients with moderate/severe ARDS across the US, of whom 217 were randomized 1:1 and received either standard of care alone or standard of care plus 2 intravenous infusions of remestemcel-L at a dose of 2 million cells/kg 3-5 days apart. This was the same remestemcel-L dosing regimen used in the earlier compassionate use program where 11 of the 12 patients were younger than 65 and 75% successfully came off ventilatory support.

Key findings in the trial were:

- Remestemcel-L showed a positive but non-significant trend in overall mortality reduction through day 60 across the entire population of treated patients (n=217), Hazard Ratio (HR) 0.86, 95% CI (0.589, 1.246)^{5,6}; in those over age 65, there was no significant reduction in mortality (HR 1.05)
- In the pre-specified population of patients under age 65 (n=123), remestemcel-L significantly reduced mortality by 46% through day 60, 26% vs 42%, Hazard Ratio (HR) 0.54, 95% CI (0.286, 1.005), p=0.048^{5,6}
- Remestemcel-L had similar treatment effects on mortality in those under 65 years, with either moderate ARDS (HR 0.56)^{6,7} or severe ARDS (HR 0.56)^{6,7}
- Standard of care changed during the course of the trial to incorporate dexamethasone, with only 2% of the first 50 patients enrolled receiving dexamethasone compared with 84% of the subsequent 172 patients; this allowed for additional exploratory analyses of remestemcel-L treatment effects in patients who received dexamethasone as part of their standard of care
- Remestemcel-L reduced mortality through day 60 by 75% compared to controls in patients under 65 who received dexamethasone as part of their standard of care, 14% vs 45%, HR 0.25, 95% CI (0.085, 0.727), p=0.006^{5,6}
- Remestemcel-L increased days alive off ventilator within 60 days and reduced time to discharge from initial hospitalization compared to controls in patients under 65 who received dexamethasone as part of their standard of care, p=0.01 and p=0.005, respectively^{5,8}

Inflammatory Bowel Disease – Crohn’s Disease and Ulcerative Colitis

A randomized, controlled study of remestemcel-L delivered by an endoscope directly to the areas of inflammation and tissue injury in up to 48 patients with medically refractory Crohn’s disease and ulcerative colitis commenced at Cleveland Clinic in October 2020. The investigator-initiated study is the first in humans using local cell delivery in the gut and will enable Mesoblast to compare clinical outcomes using this delivery method with results from an ongoing randomized, placebo-controlled trial in patients with biologic-refractory Crohn’s disease where remestemcel-L was administered intravenously.

Rexlemestrocel-L

Revascor for Chronic Heart Failure

The results from the landmark DREAM-HF randomized controlled trial in 537 treated patients with chronic heart failure with reduced left ventricular ejection fraction (HFrEF) who received rexlemestrocel-L (REVASCOR®) or control sham, demonstrated that a single dose of rexlemestrocel-L resulted in substantial and durable reductions in heart attacks, strokes, and cardiac deaths. The trial’s primary endpoint of reduction in volume overload related hospitalizations was not achieved. The results of this trial identify New York Heart Association (NYHA) class II HFrEF patients as the optimal

target population for greatest rexlemestrocel-L treatment effect, and therefore a focus for developing rexlemestrocel-L in the largest market in heart failure.

Based on the observed reduction in mortality and morbidity in this trial, Mesoblast intends to meet with the FDA to discuss potential next steps in the regulatory pathway.

MPC-06-ID for Chronic Low Back Pain due to Degenerative Disc Disease

The results from the randomized controlled trial of its allogeneic mesenchymal precursor cell (MPC) therapy rexlemestrocel-L in 404 enrolled patients with chronic low back pain (CLBP) due to degenerative disc disease (DDD) refractory to conventional treatments indicate that a single injection of rexlemestrocel-L + hyaluronic acid (HA) carrier may provide a safe, durable, and effective opioid-sparing therapy for patients with chronic inflammatory back pain due to degenerative disc disease, and that greatest benefits are seen when administered earlier in the disease process before irreversible fibrosis of the intervertebral disc has occurred.

There is a significant need for a safe, efficacious, and durable opioid-sparing treatment in patients with chronic low back pain due to severely inflamed degenerative disc disease. Mesoblast intends to meet with FDA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic discogenic lower back pain based on the observed durable reduction in pain and opioid sparing activity in the CLBP trial.

Financial Results for the Three Months Ended March 31, 2021 (third quarter FY2021)

- **Balance sheet** cash on hand of US\$158.3 million at March 31, 2021, following the successful completion of US\$110 million private placement. Private placement was led by US investor group SurgCenter Development, one of the largest private operators of ambulatory surgical centres in the US specializing in spine, orthopaedic and total joint replacement. Mesoblast entered into a contractual amendment with Hercules to extend the interest-only period of its debt facility through to at least October 2021
- **Royalty revenues** on sales of TEMCELL® HS Inj. in Japan were US\$1.9 million for the third quarter FY2021 compared to US\$2.0 million for the third quarter FY2020 as sales continue to recover from the effects of the temporary shutdown in production during mid-2020 which was undertaken in order to increase capacity to meet growing demand for the product
- **Research and Development** expenses decreased from US\$14.4 million in FY2020 to US\$12.4 million in FY2021, due to a reduction in third party clinical trial costs
- **Manufacturing** expenses were US\$7.3 million for third quarter FY2021, compared to US\$7.6 million for third quarter FY2020
- **Management and Administration** expenses increased from US\$5.7 million for third quarter FY2020 to US\$8.1 million for third quarter FY2021; this increase was predominantly due to one-off expenditure in legal and professional fees associated with regulatory and financing activities
- **Finance Costs** for borrowing arrangements with Hercules and NovaQuest were US\$3.2 million for third quarter FY2021, compared to US\$3.4 million for third quarter FY2020.

As a result of the above and other remeasurements on revaluation of assets and liabilities, the loss after tax for the third quarter FY2021 was US\$26.5 million compared to US\$15.3 million for third quarter FY2020. The net loss attributable to ordinary shareholders was 4.39 US cents per share for third quarter FY2021, compared with 2.84 US cents per share for third quarter FY2020.

Conference Call

There will be a webcast today, beginning at 8.30am AEST (Thursday, June 3); 6.30pm EDT (Wednesday, June 2, 2021). It can be accessed via:

<https://webcast.boardroom.media/mesoblast-limited/20210602/NaN60b6e20c3acee00019e165bd>

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

www.mesoblast.com

About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2040 in all major markets. The Company'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 completed Phase 3 trials of rexlemestrocel-L for advanced chronic heart failure and chronic low back pain. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease and moderate to severe acute respiratory distress syndrome. 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

References / Footnotes

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET). Centers for Disease Control and Prevention
3. Martin-Loeches et al. Pandemic and post-pandemic Influenza A (H1N1) infection in critically ill patients *Critical Care* 2011, 15:R286
4. Bonmarin I et al. Intensive care unit surveillance of influenza infection in France: the 2009/10 pandemic and the three subsequent seasons. *Euro Surveill.* 2015;20(46)
5. All p-values are descriptive and not adjusted for multiplicity
6. Hazard Ratios calculated using Cox regression proportional hazards model without adjustment; p-value from Kaplan-Meier log rank statistics
7. Interaction term between remestemcel-L treatment and ARDS severity in Cox regression proportional hazards model was not significant (p=0.98), indicating that treatment effect is not confounded by disease severity
8. Wilcoxon rank sum test

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.

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Consolidated Income Statement

	Three Months Ended March 31,		Nine Months Ended March 31,	
(in U.S. dollars, in thousands, except per share amount)	2021	2020	2021	2020
Revenue	1,915	12,201	5,461	31,455
Research & development	(12,441)	(14,379)	(45,957)	(40,922)
Manufacturing commercialization	(7,332)	(7,612)	(25,706)	(15,456)
Management and administration	(8,087)	(5,730)	(23,633)	(17,960)
Fair value remeasurement of contingent consideration	1,534	2,158	18,103	1,276
Other operating income and expenses	1,025	(442)	1,420	(67)
Finance costs	(3,227)	(3,414)	(7,193)	(9,814)
Loss before income tax	(26,613)	(17,218)	(77,505)	(51,488)
Income tax (expense)/benefit	98	1,955	754	6,158
Loss attributable to the owners of Mesoblast Limited	<u>(26,515)</u>	<u>(15,263)</u>	<u>(76,751)</u>	<u>(45,330)</u>
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)	(2.84)	(12.99)	(8.66)
Diluted - losses per share	(4.39)	(2.84)	(12.99)	(8.66)

Consolidated Statement of Comprehensive Income

	Three Months Ended March 31,		Nine Months Ended March 31,	
(in U.S. dollars, in thousands)	2021	2020	2021	2020
Loss for the period	(26,515)	(15,263)	(76,751)	(45,330)
Other comprehensive (loss)/income				
<i>Items that may be reclassified to profit and loss</i>				
Financial assets at fair value through other comprehensive income	81	94	109	(551)
Exchange differences on translation of foreign operations	(2,712)	(361)	(1,400)	(405)
Other comprehensive (loss) for the period, net of tax	(2,631)	(267)	(1,291)	(956)
Total comprehensive losses attributable to the owners of Mesoblast Limited	<u>(29,146)</u>	<u>(15,530)</u>	<u>(78,042)</u>	<u>(46,286)</u>

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of March 31, 2021	As of June 30, 2020
Assets		
Current Assets		
Cash & cash equivalents	158,263	129,328
Trade & other receivables	2,947	1,574
Prepayments	8,556	5,646
Total Current Assets	169,766	136,548
Non-Current Assets		
Property, plant and equipment	2,989	2,293
Right-of-use assets	7,247	7,978
Financial assets at fair value through other comprehensive income	1,981	1,871
Other non-current assets	3,203	3,311
Intangible assets	580,939	581,601
Total Non-Current Assets	596,359	597,054
Total Assets	766,125	733,602
Liabilities		
Current Liabilities		
Trade and other payables	24,275	24,972
Provisions	18,757	29,197
Borrowings	52,673	32,455
Lease liabilities	2,841	3,519
Total Current Liabilities	98,546	90,143
Non-Current Liabilities		
Deferred tax liability	—	730
Provisions	17,823	27,563
Borrowings	39,847	57,023
Lease liabilities	6,479	6,317
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	66,649	94,133
Total Liabilities	165,195	184,276
Net Assets	600,930	549,326
Equity		
Issued Capital	1,162,188	1,051,450
Reserves	64,251	46,634
(Accumulated losses)/retained earnings	(625,509)	(548,758)
Total Equity	600,930	549,326

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Nine Months Ended March 31,	
	2021	2020
Cash flows from operating activities		
Commercialization revenue received	4,162	5,579
Upfront and milestone payments received	—	17,500
Government grants and tax incentives received	56	1,499
Payments to suppliers and employees (inclusive of goods and services tax)	(86,029)	(57,722)
Interest received	17	533
Interest and other costs of finance paid	(4,122)	(4,165)
Income taxes paid	(35)	(7)
Net cash (outflows) in operating activities	(85,951)	(36,783)
Cash flows from investing activities		
Investment in fixed assets	(1,424)	(1,305)
Payments for licenses	—	(100)
Net cash (outflows) in investing activities	(1,424)	(1,405)
Cash flows from financing activities		
Payments of transaction costs from borrowings	(13)	—
Proceeds from issue of shares	105,584	51,559
Proceeds from issue of warrants	12,969	—
Payments for share issue costs	(1,547)	(2,211)
Payments for lease liabilities	(2,100)	(1,219)
Net cash inflows by financing activities	114,893	48,129
Net increase in cash and cash equivalents	27,518	9,941
Cash and cash equivalents at beginning of period	129,328	50,426
FX gain/(losses) on the translation of foreign bank accounts	1,417	(290)
Cash and cash equivalents at end of period	158,263	60,077