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OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR THE YEAR ENDED JUNE 30, 2021

Melbourne, Australia; August 31 and New York, USA; August 30, 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 fourth quarter and full-year ended June 30, 2021 (FY2021).

"During this calendar year we made significant progress in both regulatory and clinical outcomes for our lead product candidate, remestemcel-L, after experiencing a disappointing set-back last year" said Silviu Itescu, Chief Executive of Mesoblast. "We are pleased with recent recommendations by FDA's CBER to meet with the review team and address remaining CMC items for remestemcel-L in the treatment of steroid-refractory acute graft versus host disease in children. Additionally, our most recent meeting with the FDA has provided clarity on the pathway towards an emergency use authorization for remestemcel-L in the treatment of COVID ARDS."

Operational Highlights

Remestemcel-L – Outcome of recent meeting with FDA on regulatory pathway for emergency use authorization in the treatment of COVID-19 ARDS:

- Mesoblast met with the United States Food & Drug Administration (FDA) in regard to potential emergency use authorization (EUA) for remestemcel-L in the treatment of ventilator-dependent patients with moderate or severe acute respiratory distress syndrome (ARDS) due to COVID-19
- The FDA advised Mesoblast that an additional clinical study in COVID ARDS would be required which, if statistically positive, could provide a dataset in conjunction with the recently completed 222 patient clinical study that might be sufficient to support an EUA
- FDA provided guidance that the existing COVID ARDS Investigational New Drug (IND) file and future submissions for remestemcel-L in this indication may continue to cross-reference manufacturing information in Biologics License Application (BLA) 125706 for pediatric steroid-refractory acute graft versus host disease (SR-aGVHD)
- FDA indicated that potency assays must be established and agreed prior to commencement of the proposed Phase 3 clinical trial
- FDA indicated that the potency assays currently in development appeared to be reasonable based on in vitro results provided in the briefing document, the in vitro activity of the product appears to be relatively well established, though the relationship between in vitro activity and the product's actual mechanism of action remains theoretical
- Mesoblast intends to meet with FDA's Office of Tissue and Advanced Therapies (OTAT) in Q4 CY21 to address potency assays for remestemcel-L in relation to SR-aGvHD, attributes which we believe to be also relevant to COVID ARDS
- Mesoblast has entered into a license and collaboration agreement with Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the treatment of acute respiratory distress syndrome (ARDS) including that associated with COVID-19. The agreement remains subject to certain closing conditions, including time to analyze the results from the COVID-19 ARDS trial

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 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 SR-aGVHD in children

- The FDA's Center for Biologics Evaluation and Research (CBER) has recommended that Mesoblast as a next step discuss with CBER's review team at OTAT our approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assays, which could support a resubmission of the current BLA
- Mesoblast intends to meet with FDA's OTAT in Q4 CY21, to address potency assays and other outstanding CMC items

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

- Mesoblast expects to receive feedback from the FDA in the next quarter on the potential pathways to US regulatory approval for its rexlemestrocel-L technology platform following the recently completed Phase 3 trials in patients with chronic heart failure and chronic low back pain (CLBP) due to degenerative disc disease
- Mesoblast and its partner for CLBP in Europe and Latin America, Grünenthal, amended their collaboration agreement in line with a strategy to achieve regulatory harmonization, cost efficiencies and streamlined timelines aiming to leverage the results from a planned US trial in support of potential product approvals in both US and EU

Manufacturing

- During fiscal year 2021, Mesoblast continued to invest in manufacturing of remestemcel-L as part of its readiness strategy for potential FDA approval and commercial launch, with 92% of total manufacturing spend being for commercial readiness and next generation, pre-launch inventory and clinical cell supply for life cycle management
- Considerable effort has been focused on development and validation of specific CMC items necessary for Mesoblast's potential resubmission of the BLA for remestemcel-L, as well as potency assay work that will support both the aGVHD BLA resubmission and the IND for the Phase 3 trial COVID ARDS
- Work has also continued on Mesoblast's proprietary technology that facilitates the increase in yields necessary for the long-term commercial supply of its product candidates, and next generation manufacturing processes to reduce labor, drive down cost of goods and improve manufacturing efficiencies

Financial Highlights

- US$136.9 million cash on hand at June 30, 2021
- Sales of TEMCELL® HS Inj.[1] in Japan by licensee JCR for the treatment of aGVHD have re-established a steady growth trajectory after plant capacity was expanded to meet growing demand
- Revenue from TEMCELL® royalties increased by 10% from the prior year period to US$7.2 million in the year ended June 30, 2021
- Mesoblast has entered into a contractual amendment to extend the interest-only period of its current senior debt facility through to at least January 2022 and is in active discussions to refinance the facility
- Ongoing investment in remestemcel-L platform to support the regulatory pathway to potential approval, manufacturing scale up and life cycle management
- We expect to recognize the existing US$21.9 million of remestemcel-L pre-launch inventory on the balance sheet if we receive FDA approval

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DETAILED CLINICAL ACTIVITIES FOR THE FISCAL YEAR FY2021

Remestemcel-L

Acute Respiratory Distress Syndrome due to COVID-19

Mesoblast recently presented results from the randomized controlled trial of remestemcel-L in 222 ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) at the biennial Stem Cells, Cell Therapies, and Bioengineering in Lung Biology and Diseases conference hosted by the University of Vermont, Burlington, VT, and at the International Society for Cell & Gene Therapy (ISCT) Scientific Signatures Series event on Cell and Gene-Based Therapies in Lung Diseases and Critical Illnesses.

The presented data included improved respiratory function in patients treated with remestemcel-L, as well as 90-day survival outcomes showing remestemcel-L significantly reduced mortality by 48% at 90 days compared to controls in a pre-specified exploratory analysis of 123 treated patients under 65 years old. The trial had been halted after the third interim analysis since the 30-day primary endpoint would not be attained.

Key presentation findings were:

- Remestemcel-L reduced mortality by 48% at 90 days compared to controls in a pre-specified analysis of 123 treated patients under 65 years old, 26% vs 44%, Hazard Ratio (HR) 0.52, 95% CI (0.277, 0.964), p=0.035.[2,3] This compares favourably with the 46% mortality reduction reported at 60 days (p=0.048)[2,3] and indicates a durable treatment benefit in this patient population
- Remestemcel-L showed benefit in an exploratory analysis in patients on dexamethasone as part of their standard of care, with 90-day mortality being reduced by 77% compared to controls under 65 who received dexamethasone, 14% vs 48%, HR 0.23, 95% CI (0.080, 0.681), p=0.0037[2,3]
- These survival benefits were accompanied by improvements relative to controls in pre-specified secondary endpoints of ventilator-free days, respiratory function as assessed by ARDS severity, and overall clinical improvement on a 7-point ordinal scale
- Despite a treatment-related improvement in respiratory function at day 7, there was no mortality reduction in the 97 treated patients over age 65, suggesting the potential need for more prolonged or higher dosing of anti-inflammatory therapy in these patients who may have a more exuberant inflammatory response associated with defective immune-mediated viral clearance mechanisms

Mesoblast plans to move forward with an additional Phase 3 trial in COVID-19 ARDS with the next step being to agree with the FDA the final protocol and potency assay.

Inflammatory Bowel Disease – Crohn's Disease and Ulcerative Colitis

A randomized, controlled study of remestemcel-L delivered by an endoscope directly to 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

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.

The incidence of heart attacks and strokes were reduced by 60% over a median follow-up period of 30 months following a single dose of rexlemestrocel-L in the entire population of 537 treated patients. The incidence of death from cardiovascular causes was reduced by 60% in the 206 patients with NYHA class II disease, a significant reduction which was evident in both ischemic and non-ischemic subgroups as well as diabetic and nondiabetic patients.

The results also show that the NYHA class II patients in the control group, following an initial period of approximately 20 months of disease stability, progressed to cardiac death rates in-line with NYHA class III patients. NYHA class II patients treated with a single dose of rexlemestrocel-L did not show such cardiac death progression.

The combination of the three pre-specified outcomes of cardiac death, heart attack or stroke into a single composite outcome - called the three-point major adverse cardiovascular events (MACE) is a well-established endpoint used by the FDA to determine cardiovascular risk. Rexlemestrocel-L reduced this three-point MACE by 30% compared to controls across the entire population of 537 treated patients. In the NYHA class II subgroup of 206 patients, rexlemestrocel-L reduced the three-point MACE by 55% compared to controls.

Mesoblast expects feedback from the FDA in the next quarter on the potential pathway to US regulatory approval for rexlemestrocel-L in patients with chronic heart failure.

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. The trial's composite outcomes of pain reduction together with functional responses to treatment were not met by either MPC group.

The rexlemestrocel-L+HA treatment group achieved substantial and durable reductions in CLBP compared to control through 24 months across the entire evaluable study population (n=391) compared with saline controls. Greatest pain reduction was observed in the pre-specified population with CLBP of shorter duration than the study median of 68 months (n=194) and subjects using opioids at baseline (n=168) with the rexlemestrocel-L+HA group having substantially greater reduction at all time points (1, 3, 6, 12, 18 and 24 months) compared with saline controls. There was no appreciable difference in the safety of MPC groups compared to saline control over the 24-month period of follow-up in the entire study population. In subjects using opioids at baseline, the MPC+HA demonstrated a reduction in the average opioid dose over 24 months, while saline control subjects had essentially no change.

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 has filed a request and expects to receive feedback from the FDA on the pathway to US regulatory approval in patients with chronic low back pain due to degenerative disc disease.

Intellectual Property

Mesoblast has an extensive patent portfolio with over 1,000 patents and patent applications across 77 patent families, and patent terms extending through 2041. These patents cover composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells, and provide strong commercial protection for our products in all major markets, including the United States, Europe,

Japan and China. During the fiscal year Mesoblast has significantly expanded its patent portfolio, focusing on areas of its strategic commercial interests.

Licensing agreements with JCR, Grünenthal, Tasly and Takeda highlight the strength of Mesoblast's extensive intellectual property portfolio covering mesenchymal lineage cells. Mesoblast will continue to use its patents to prosecute its commercial rights as they relate to its core strategic product portfolio. When consistent with the Company's strategic objectives, it may consider providing third parties with commercial access to its patent portfolio.

DETAILED FINANCIAL RESULTS

Financial Results for the Year Ended June 30, 2021 (FY2021)

- **Balance sheet** cash on hand of US$136.9 million at June 30, 2021.

  In August we entered into a contractual amendment to extend the interest-only period of its current senior debt facility to at least January 2022 and as a result no loan repayments will be required prior to January 2022. Mesoblast is in active discussions to refinance the facility.

- **Royalty revenues** on sales of TEMCELL® HS Inj. in Japan increased by 10% to US$7.2 million for the year ended June 30, 2021 compared to US$6.6 million for the year ended June 30, 2020. Sales of TEMCELL by Mesoblast licensee in Japan JCR for the treatment of aGVHD have re-established a steady growth trajectory after plant capacity was expanded to meet growing demand.

- **Milestone revenue** FY2020 included US$25.0 million in rexlemestrocel-L upfront & milestone payments from Grünenthal and Tasly, which was not reported in FY2021

- **Research and Development** expenses decreased from US$56.2 million in FY2020 to US$53.0 million in FY2021, due to a reduction in third party clinical trial costs; 54% (US$28.5 million) of total spend related to remestemcel-L development, including clinical, medical & regulatory support ($14.8 million), process development (including potency assays & support costs) (US$9.5 million), and COVID ARDS Phase 3 clinical trial (US$4.2 million).

- **Manufacturing** expenses increased by US$7.4 million to US$32.7 million for FY2021, compared to US$25.3 million for FY2020; 92% (US$30.2 million) of total spend related to remestemcel-L, including: pre-launch inventory (US$13.1 million), clinical cell supply for life cycle management (US$3.5 million), commercial readiness and next generation processes (US$13.6 million) to improve cost efficiencies and yields of remestemcel-L to support long-term commercial supply for SR-aGVHD and COVID ARDS.

  We expect to recognize the existing US$21.9 million of remestemcel-L pre-launch inventory on the balance sheet if we receive FDA approval.

- **Management and Administration** expenses increased from US$25.6 million for FY2020 to US$30.9 million for FY2021; this increase was predominantly due to costs associated with insurance, BLA filing, debt refinancing and other corporate transactions.

- **Finance Costs** predominantly for borrowing arrangements with Hercules and NovaQuest were US$10.7 million for FY2021, compared to US$14.1 million for FY2020.

As a result of the above and other remeasurements on revaluation of assets and liabilities, the loss after tax for FY2021 was US$98.8 million compared to US$77.9 million for FY2020. The net loss attributable to ordinary shareholders was 16.33 US cents per share for FY2021, compared with 14.74 US cents per share for FY2020.

Conference Call

There will be a webcast today, beginning at 9.00am AEST (Tuesday, August 31); 7.00pm EDT (Monday, August 30, 2021). It can be accessed via:
https://webcast.boardroom.media/mesoblast-limited/20210826/NaN61036c41df5665001c97fc67

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 2041 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. All p-values are descriptive and not adjusted for multiplicity
3. Hazard Ratios calculated using Cox regression proportional hazards model without adjustment; p-value from Kaplan-Meier log rank statistics

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

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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

(in U.S. dollars, in thousands, except per share amount)	Year Ended June 30, 2021	2020
Revenue	7,456	32,156
Research & development	(53,012)	(56,188)
Manufacturing commercialization	(32,719)	(25,309)
Management and administration	(30,867)	(25,609)
Fair value remeasurement of contingent consideration	18,687	1,380
Other operating income and expenses	1,539	324
Finance costs	(10,714)	(14,109)
Loss before income tax	**(99,630)**	**(87,355)**
Income tax benefit	819	9,415
Loss attributable to the owners of Mesoblast Limited	**(98,811)**	**(77,940)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(16.33)	(14.74)
Diluted - losses per share	(16.33)	(14.74)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Year Ended June 30, 2020	2020
Loss for the period	**(98,811)**	**(77,940)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	(1,524)	1,146
Items that will not be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	209	(446)
Other comprehensive (loss)/income for the period, net of tax	**(1,315)**	**700**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(100,126)**	**(77,240)**

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of June 30, 2021	As of June 30, 2020
Assets		
Current Assets		
Cash & cash equivalents	136,881	129,328
Trade & other receivables	4,842	1,574
Prepayments	6,504	5,646
Total Current Assets	**148,227**	**136,548**
Non-Current Assets		
Property, plant and equipment	3,021	2,293
Right-of-use assets	9,119	7,978
Financial assets at fair value through other comprehensive income	2,080	1,871
Other non-current assets	1,724	3,311
Intangible assets	580,546	581,601
Total Non-Current Assets	**596,490**	**597,054**
Total Assets	**744,717**	**733,602**
Liabilities		
Current Liabilities		
Trade and other payables	19,598	24,972
Provisions	18,710	29,197
Borrowings	53,200	32,455
Lease liabilities	2,765	3,519
Total Current Liabilities	**94,273**	**90,143**
Non-Current Liabilities		
Deferred tax liability	—	730
Provisions	17,017	27,563
Borrowings	41,045	57,023
Lease liabilities	8,485	6,317
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**69,047**	**94,133**
Total Liabilities	**163,320**	**184,276**
Net Assets	**581,397**	**549,326**
Equity		
Issued Capital	1,163,153	1,051,450
Reserves	65,813	46,634
(Accumulated losses)/retained earnings	(647,569)	(548,758)
Total Equity	**581,397**	**549,326**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Year Ended June 30, 2021	2020
Cash flows from operating activities		
Commercialization revenue received	6,121	7,676
Upfront and milestone payments received	—	17,500
Government grants and tax incentives received	68	1,577
Payments to suppliers and employees (inclusive of goods and services tax)	(106,920)	(77,710)
Interest received	17	546
Interest and other costs of finance paid	(5,932)	(5,947)
Income taxes paid	(35)	(7)
Net cash (outflows) in operating activities	**(106,681)**	**(56,365)**
Cash flows from investing activities		
Investment in fixed assets	(1,647)	(2,096)
Payments for contingent consideration		(1,027)
Payments for licenses	—	(150)
Net cash (outflows) in investing activities	**(1,647)**	**(3,273)**
Cash flows from financing activities		
Proceeds from borrowings	—	512
Repayment of borrowings	—	(512)
Payments of transaction costs from borrowings	(13)	—
Proceeds from issue of shares	106,268	144,946
Proceeds from issue of warrants	12,969	—
Payments for share issue costs	(1,827)	(6,277)
Payments for lease liabilities	(2,931)	(1,625)
Net cash inflows by financing activities	**114,466**	**137,044**
Net increase in cash and cash equivalents	6,138	77,406
Cash and cash equivalents at beginning of period	129,328	50,426
FX gain/(losses) on the translation of foreign bank accounts	1,415	1,496
Cash and cash equivalents at end of period	**136,881**	**129,328**

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