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mesoblast

OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR THE PERIOD ENDED SEPTEMBER 30, 2021

Melbourne, Australia; November 24 and New York, USA; November 23, 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 first quarter ended September 30, 2021.

"We are pleased to have entered into a strategic financing partnership with leading global investment management firm Oaktree Capital as we focus on bringing our first product to the US market and in line with our commercial growth strategy over the next five years," said Silviu Itescu, Chief Executive of Mesoblast"

Financial & Operational Highlights

- Successfully entered into a refinancing and expansion of our senior debt facility with Oaktree Capital Management. The new US$90 million, 5-year secured facility has a 3-year interest only period after which time 40% of the principal amortizes over two years and a final payment due no later than November 2026.
- Cash on hand at the end of the quarter was US$116.0 million
- Revenues from TEMCELL® HS Inj.[1] royalties in Japan were US$2.4 million, an increase of 22% on the previous quarter, and of 90% on the comparative quarter last year
- Net cash operating usage was US$19.6 million for the quarter, a reduction of US$8.6 million on the comparative quarter
- Loss after tax improved US$1.9 million on the comparative quarter
- Results published in the latest issue of the peer-reviewed journal *Bone Marrow Transplantation*[2] showed that children with steroid-refractory acute graft versus host disease (SR-aGVHD) and biomarkers predictive for highest mortality had 64% survival when treated with remestemcel-L compared with only 10% survival when treated with other available therapies, including ruxolitinib or other biologics
- These data provide further support for the proposed anti-inflammatory mechanism of action of remestemcel-L and its immunomodulatory activity in patients with SR-aGVHD, resulting in improved survival outcomes
- At the upcoming scheduled meeting with United States Food & Drug Administration's (FDA) Office of Tissue and Advanced Therapies (OTAT), Mesoblast will address the appropriateness of potency assays related to remestemcel-L's proposed anti-inflammatory mechanism of action as well as the outstanding chemistry, manufacturing and controls (CMC) items which could support a resubmission of the current Biologics License Application (BLA) for remestemcel-L in the treatment of SR-aGVHD in children
- Mesoblast met with the 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 that an additional clinical study which showed statistically positive outcomes in conjunction with the recently completed 222 patient trial may be sufficient to provide a dataset in support of an EUA
- Results from the randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with New York Heart Association (NYHA) class II and class III chronic heart failure (CHF) with low ejection fraction (HFrEF) were presented as a late breaking presentation at the American Heart Association (AHA) annual Scientific Sessions during a featured program titled 'Building on the Foundations of Treatment: Advances in Heart Failure Therapy'

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- The trial's co-principal investigator Dr Emerson Perin, Medical Director of Texas Heart Institute, and Clinical Professor, Baylor College of Medicine, presented new results from the landmark study showing a significant relationship between presence of systemic inflammation as quantified by high-sensitivity C-reactive protein (hs-CRP) and treatment benefit with rexlemestrocel-L on risk of cardiovascular mortality, heart attacks or strokes
- Mesoblast is in ongoing discussions with the FDA on the potential pathways to US regulatory approval for its rexlemestrocel-L product candidate in heart failure patients at high risk of cardiovascular mortality, heart attacks or strokes

DETAILED CLINICAL ACTIVITIES DURING FOR THE PERIOD

Remestemcel-L

Steroid-refractory acute graft versus host disease (SR-aGVHD) in children:

Results published in the peer-reviewed journal Bone Marrow Transplantation[2] showed that children with SR-aGVHD and biomarkers predictive for highest mortality had 64% survival when treated with remestemcel-L compared with only 10% survival when treated with other available therapies.

The study compared outcomes in 25 children from Mesoblast's Phase 3 trial of remestemcel-L in SR-aGVHD with 27 closely matched children from the Mount Sinai Acute GVHD International Consortium (MAGIC)[3] who participated in a prospective natural history study and were matched for the Phase 3 trial entry criteria. The objective of the study was to evaluate whether outcomes differed according to treatment with remestemcel-L vs other therapies in children at highest risk of death, namely those with baseline MAGIC Algorithm Probability (MAP) biomarker levels ≥0.291, a level predictive of very high mortality and poor responses to therapy in SR-aGVHD. MAP combines the serum concentrations of two biomarkers, Reg3α and ST2, into a single value that predicts long-term outcomes and significant GI tract damage.

MAP levels ≥0.291 were present in 48% of remestemcel-L treated children (12/25) and 37% of the MAGIC cohort (10/27). Treatment with remestemcel-L resulted in 67% Day 28 Overall Response and 64% Day 180 overall survival compared with 10% Day 28 Overall Response and 10% Day 180 survival in the MAGIC cohort (both p=0.01) when treated with various biologics, including ruxolitinib. These results extend previous observations showing that children who achieved clinically meaningful responses and survival after treatment with remestemcel-L had significant reductions in the ST2 biomarker of inflammation, consistent with healing of the GI tract.[4]

These data provide further support for the proposed anti-inflammatory mechanism of action of remestemcel-L and its immunomodulatory activity in patients with SR-aGVHD, resulting in improved survival outcomes. At its upcoming scheduled meeting with FDA's OTAT, Mesoblast will address the appropriateness of potency assays related to remestemcel-L's proposed anti-inflammatory mechanism of action as well as the outstanding CMC items which could support a resubmission of the current BLA for remestemcel-L in the treatment of SR-aGVHD in children with a six month review.

Acute Respiratory Distress Syndrome (ARDS) due to COVID-19

Early this quarter, Mesoblast met with the FDA in regard to potential EUA for remestemcel-L in the treatment of ventilator-dependent patients with moderate or severe 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 BLA 125706 for pediatric 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

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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 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.

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.

Rexlemestrocel-L

Chronic Heart Failure

Data from the randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with NYHA class II and class III HFrEF were presented as a late breaking presentation at the AHA annual Scientific Sessions during a featured program titled 'Building on the Foundations of Treatment: Advances in Heart Failure Therapy.'

The trial's co-principal investigator Dr Emerson Perin, Medical Director of Texas Heart Institute, and Clinical Professor, Baylor College of Medicine, presented new results from the landmark study showing a significant relationship between presence of systemic inflammation as quantified by high-sensitivity C-reactive protein (hs-CRP) and treatment benefit with rexlemestrocel-L on risk of cardiovascular mortality, heart attacks or strokes

The presentation highlighted that a single dose of rexlemestrocel-L on top of standard care versus standard of care alone:

- Reduced the incidence of heart attacks or strokes across all 537 NYHA class II or class III treated patients
- Reduced the incidence of heart attacks or strokes by an even greater amount in 301 patients with high levels inflammation
- Reduced the incidence of cardiovascular death in NYHA class II patients with the greatest effect seen in patients with high levels of inflammation
- Did not further reduce the frequency of hospitalization for worsening HF symptoms as previously reported

Whereas most traditional treatments address the congestion or fluid overload associated with heart failure, rexlemestrocel-L addresses the inflammation that is at the centre of advanced chronic heart failure – widely regarded as the leading cause of death in the developed world.

The ability of rexlemestrocel-L to significantly impact cardiac death, heart attacks and strokes on top of maximal HFrEF therapy reflects the unique mechanisms-of-action of this allogeneic cellular therapy on reduction of inflammation and improved microvasculature. The unchecked intra-cardiac inflammation in HFrEF patients causes progressive loss of heart muscle, replacement with scar tissue, and death. Persistent inflammation in the blood circulation also results in accelerated atherosclerosis with plaque progression and instability resulting in plaque rupture and potential blockage of major arteries, resulting in high rates of heart attacks and strokes in chronic HFrEF patients.

Rexlemestrocel-L is believed to reduce inflammatory cytokine production by immune cells, generating improved local networks of blood vessels within the damaged heart and reducing risk of plaque rupture in major arteries. The observed relationship between systemic inflammation and degree of benefit from treatment with rexlemestrocel-L supports the importance of the anti-inflammatory mechanism-of-action of rexlemestrocel-L in addressing the high-risk of mortality and morbidity in HFrEF patients.

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DETAILED FINANCIAL HIGHLIGHTS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2021 (FIRST QUARTER FY2022)

- **Cash on hand** at the end of the quarter was US$116.0 million
- **Net operating cash** usage was US$19.6 million for the quarter, a reduction of US$8.6 million on the comparative quarter.
- **Total Revenue** was US$3.6 million for the first quarter FY2022, an increase of US$2.3 million on the comparative quarter due to growth in royalties and US$1.2 million of milestone revenue given Takeda received approval to manufacture and market Alofisel® (darvadstrocel) in Japan for the treatment of complex perianal fistulas in patients with non-active or mildly active luminal Crohn's Disease.

  Within revenue, royalties from TEMCELL® HS Inj.[1] in Japan were US$2.4 million, an increase of 22% on the previous quarter, and of 90% on the comparative quarter last year.
- **Research & Development expenses** reduced by US$10.0 million (52%), down to US$9.3 million for the first quarter FY2022 from US$19.3 million for the first quarter FY2021 as clinical trial activities for our COVID-19 ARDS, CLBP and CHF product candidates reduced given clinical trial recruitment and data analysis is now complete.
- **Manufacturing expense** reduced by US$4.4 million (37%) down to US$7.5 million for the first quarter FY2022 from US$11.9 million for the first quarter FY2021 due to a reduction in process development activities. During the quarter we continued to build our pre-launch inventory levels of remestemcel-L to support the long-term commercial supply for SR-aGVHD and COVID ARDS.

  We expect to recognize the US$26.0 million balance of remestemcel-L pre-launch inventory, and the balance of any further production completed at that time, on our balance sheet if we receive FDA approval.
- **Management and Administration** reduced by US$1.8 million (23%), down to US$5.9 million for the first quarter FY2022 from US$7.7 million for the first quarter FY2021 as employee compensation costs were reduced.
- **Remeasurement of Contingent Consideration** reduced to a gain of US$0.3 million for the first quarter FY2022 whereas a gain of US$15.1 million was recognized in the first quarter FY2021 reflecting a reduction in future third party payments.
- **Finance Costs** predominantly for borrowing arrangements with Hercules and NovaQuest were US$3.6 million for the first quarter FY2022, compared to US$2.9 million for the first quarter FY2021.

Loss after tax improved US$1.9 million, down to US$22.6 million for the first quarter FY2022 compared to US$24.5 million for the first quarter FY2021.The net loss attributable to ordinary shareholders was 3.49 US cents per share for the first quarter FY2022, compared with 4.21 US cents per share for the first quarter FY2021.

Conference Call

There will be a webcast today, beginning at 9.00am AEDT (Wednesday, November 24); 5.00pm EST (Tuesday, November 23). It can be accessed via: https://webcast.openbriefing.com/8205/

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

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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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L stromal cell technology platforms. 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. Rexlemestrocel-L is in development for advanced chronic heart failure and chronic low back pain. 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. Kasikis S., et al. Mesenchymal stromal cell therapy induces high responses and survival in children with steroid refractory GVHD and poor risk. *Bone Marrow Transplantation* 2021; https://doi.org/10.1038/s41409-021-01442-3
3. Mount Sinai Acute GVHD International Consortium (MAGIC) - a group of ten BMT centers throughout the US and Europe whose purpose is to conduct ground-breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD therapy
4. Presented at the annual meeting of the American Society of Hematology (ASH) 2020

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

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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)	Three Months Ended September 30, 2021	2020
Revenue	3,594	1,305
Research & development	(9,328)	(19,278)
Manufacturing commercialization	(7,537)	(11,924)
Management and administration	(5,878)	(7,680)
Fair value remeasurement of contingent consideration	280	15,107
Other operating income and expenses	(178)	99
Finance costs	(3,660)	(2,903)
Loss before income tax	**(22,707)**	**(25,274)**
Income tax (expense)/benefit	62	730
Loss attributable to the owners of Mesoblast Limited	**(22,645)**	**(24,544)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(3.49)	(4.21)
Diluted - losses per share	(3.49)	(4.21)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2021	2020
Loss for the period	**(22,645)**	**(24,544)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	(349)	408
Items that will not be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	154	81
Other comprehensive (loss)/income for the period, net of tax	**(195)**	**489**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(22,840)**	**(24,055)**

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of September 30, 2021	As of June 30, 2021
Assets		
Current Assets		
Cash & cash equivalents	115,956	136,881
Trade & other receivables	5,627	4,842
Prepayments	4,637	6,504
Total Current Assets	**126,220**	**148,227**
Non-Current Assets		
Property, plant and equipment	2,750	3,021
Right-of-use assets	8,485	9,119
Financial assets at fair value through other comprehensive income	2,234	2,080
Other non-current assets	1,952	1,724
Intangible assets	580,178	580,546
Total Non-Current Assets	**595,599**	**596,490**
Total Assets	**721,819**	**744,717**
Liabilities		
Current Liabilities		
Trade and other payables	16,263	19,598
Provisions	19,649	18,710
Borrowings	53,847	53,200
Lease liabilities	3,140	2,765
Total Current Liabilities	**92,899**	**94,273**
Non-Current Liabilities		
Deferred tax liability	—	—
Provisions	16,465	17,017
Borrowings	42,651	41,045
Lease liabilities	7,558	8,485
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**69,174**	**69,047**
Total Liabilities	**162,073**	**163,320**
Net Assets	**559,746**	**581,397**
Equity		
Issued Capital	1,163,492	1,163,153
Reserves	66,468	65,813
(Accumulated losses)/retained earnings	(670,214)	(647,569)
Total Equity	**559,746**	**581,397**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2021	2020
Cash flows from operating activities		
Commercialization revenue received	1,995	682
Government grants and tax incentives received	24	17
Payments to suppliers and employees (inclusive of goods and services tax)	(20,223)	(27,484)
Interest received	4	13
Interest and other costs of finance paid	(1,407)	(1,389)
Income taxes paid	—	(6)
Net cash (outflows) in operating activities	**(19,606)**	**(28,167)**
Cash flows from investing activities		
Investment in fixed assets	(99)	(81)
Net cash (outflows) in investing activities	**(99)**	**(81)**
Cash flows from financing activities		
Payments of transaction costs from borrowings	(100)	—
Proceeds from issue of shares	147	8,134
Payments for share issue costs	(104)	(897)
Payments for lease liabilities	(686)	(695)
Net cash inflows by financing activities	**(743)**	**6,542**
Net decrease in cash and cash equivalents	(20,448)	(21,706)
Cash and cash equivalents at beginning of period	136,881	129,328
FX gain/(losses) on the translation of foreign bank accounts	(477)	501
Cash and cash equivalents at end of period	**115,956**	**108,123**

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