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MESOBLAST REPORTS OPERATIONAL AND FINANCIAL HIGHLIGHTS FOR QUARTER ENDED DECEMBER 31, 2022

Melbourne, Australia: February 28 and New York, USA: February 27, 2023: 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 December 31, 2022.

Dr. Silviu Itescu, Chief Executive of Mesoblast, commenting on the results said, "There is an urgent need for a therapy that improves the dismal survival outcomes in children with steroid-refractory acute graft versus host disease (SR-aGVHD),[1,2] a potentially life-threatening complication of an allogeneic bone marrow transplant for the treatment of blood cancers. With the resubmission of the BLA filing for remestemcel-L we are one step closer to bringing this important product candidate to the market."

"In addition, Mesoblast has been granted Regenerative Medicine Advanced Therapy (RMAT) designation for rexlemestrocel-L for chronic lower back pain (CLBP) associated with degenerative disc disease and we look forward to further interactions with FDA, aiming to enroll the first patients in the pivotal trial by the middle of this year.

I am also pleased to announce that results from our Phase 3 chronic heart failure trial, DREAM-HF, in patients with reduced ejection fraction (HFrEF) was today published in the world's leading cardiology journal - the *Journal of the American College of Cardiology (JACC),*[4] highlighting the potential for rexlemestrocel-L to make a key difference in patient outcomes including mortality, heart attack or stroke."

FINANCIAL HIGHLIGHTS

Revenue from royalties on sales of TEMCELL® HS Inj.[4,5] sold in Japan by our licensee were US$1.9 million for the quarter ended December 31, 2022. On a constant currency basis, sales for the quarter ended December 31, 2022, were US$2.1 million[5], compared with US$2.3 million for the quarter ended December 31, 2021.

Net cash usage for operating activities was US$16.5 million for the quarter ended December 31, 2022. This represents a 9% reduction (US$1.7 million) from the comparative quarter in FY2022, and a 46% reduction (US$14.1 million) from the comparative quarter in FY2021.

Cash on hand at the end of the quarter was $67.6 million. Up to an additional US$40.0 million may be drawn from existing financing facilities subject to achieving certain milestones.

OPERATIONAL HIGHLIGHTS

Biologics License Application (BLA) resubmitted for remestemcel-L in treatment of children with steroid-refractory graft versus host disease (SR-aGVHD) to the US Food and Drug Administration (FDA) on January 31, 2023.

Presentations of peer-reviewed studies at Tandem Meeting of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). The data from both studies formed key components of the BLA resubmission

- Long-term survival in children treated with remestemcel-L for SR-aGVHD
- The immunomodulatory activity of remestemcel-L on T cell activation *in vitro* is a direct measure of product potency and correlates with clinical outcomes in pediatric patients with SR-aGVHD.

Regenerative Medicine Advanced Therapy (RMAT) designation granted by FDA for rexlemestrocel-L in the treatment of chronic low back pain (CLBP) associated with disc degeneration, in combination with hyaluronic acid (HA) as delivery agent for injection into the lumbar disc. Preparations underway to commence pivotal study.

DREAM-HF Phase 3 trial results published in the premier peer-reviewed journal for cardiovascular medicine, the *Journal of the American College of Cardiology (JACC)*.

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OPERATIONAL RESULTS AND NEAR-TERM MILESTONES

Remestemcel-L

Activities regarding remestemcel-L for steroid resistant acute graft versus host disease (SR-aGVHD) in children

Mesoblast filed the Biologics License Application (BLA) resubmission with the US Food and Drug Administration (FDA) at the end of January. The resubmission contains substantial new information in response to the Complete Response Letter (CRL) received in September 2020 to the BLA for remestemcel-L. Specifically, the resubmission contains the following:

- new long-term survival data for children enrolled in the Phase 3 trial showing durability of treatment effect through at least four years,
- new data showing remestemcel-L's treatment benefit in high-risk disease activity and on survival in propensity-matched studies of children in the Phase 3 trial and controls stratified by validated biomarkers for high-risk disease,
- new analyses of data obtained prospectively showing that the validated potency assay which was in place and used to release product for the 54-patient Phase 3 clinical trial measures a key product attribute which reflects the primary mechanism of action of remestemcel-L in children with SR-aGVHD, correlates with the product's *in vivo* bioactivity, and predicts overall survival outcomes,
- new analyses of data obtained prospectively relating to manufacturing changes implemented during product development, prior to Phase 3, to progressive increases in potency and to improved survival outcomes in larger studies of remestemcel-L under expanded access in children with SR-aGVHD,
- new data showing that the validated potency assay has low variability and can adequately demonstrate manufacturing consistency and reproducibility, and
- establishment of a new specification for release of commercial product based on extensive clinical data which provides assurance that future batches of remestemcel-L will have attributes supportive of expected survival outcomes.

Data related to the long-term survival benefit and validated potency assay were presented at the 2023 Tandem Meetings (ASTCT-CIBMTR) held this month. The new results come from a four-year observational survival study performed by the Center for International Blood and Marrow Transplant Research (CIBMTR) on 51 evaluable patients with SR-aGVHD who were enrolled in Mesoblast's phase 3 clinical trial of remestemcel-L.

Overall survival in the remestemcel-L cohort was 63% at 1 year, 51% at 2 years, and 49% at 4 years, while across four recently published studies of children or adults with SR-aGVHD who received best available therapy (BAT) or the only FDA-approved agent for adults, survival rates of 40-49% at 1 year and 25%-38% at 2 years were seen.[6-9]

Rexlemestrocel-L

Activities regarding rexlemestrocel-L for discogenic chronic low back pain (CLBP)

This month the FDA granted RMAT designation for rexlemestrocel-L in the treatment of CLBP associated with degenerative disc disease, in combination with hyaluronic acid (HA) as delivery agent for injection into the lumbar disc.

RMAT designations aim to expedite the development of regenerative medicine therapies intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for the disease or condition. An RMAT designation for rexlemestrocel-L provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a BLA.

There is a significant need for a safe, effective, and durable opioid-sparing treatment in patients with CLBP associated with degenerative disc disease. Mesoblast has previously gained alignment with the FDA on the key metrics for a pivotal Phase 3 study of rexlemestrocel-L which seeks to replicate the significant reduction in pain seen in the first Phase 3 trial. FDA has confirmed that 12-month reduction in pain is an approvable indication, with key secondary measures of improvement in function and reduced opioid usage. Preparations underway to initiate a pivotal Phase 3 trial by mid-CY2023.

Activities regarding rexlemestrocel-L for chronic heart failure with reduced ejection fraction (HFrEF) [13]

Today's publication of the DREAM-HF Phase 3 trial results[3] in the premier peer-reviewed journal for cardiovascular medicine, the *Journal of the American College of Cardiology (JACC)* showed that rexlemestrocel-L strengthened heart function at 12 months, as measured by left ventricular ejection fraction (LVEF), and decreased cardiovascular death, myocardial infarction or stroke in patients with chronic HFrEF over a mean follow-up of 30 months.

The study enrolled patients across 51 sites in North America and the results showed that a single intra-myocardial injection of 150 million cells of rexlemestrocel-L

- improved LVEF from baseline to 12 months to a significantly greater extent than controls across all patients with available echocardiograms (p=0.021), with maximal benefit seen in patients with active inflammation as measured by the presence of baseline hsCRP ≥2mg/L (p=0.008)
- reduced risk of MI or stroke by 57% (HR 0.43; 95% CI [0.23, 0.78]) in all treated patients compared with controls
- reduced risk of MI or stroke by 75% (HR 0.25; 95% CI [0.09, 0.68]) in patients with inflammation (baseline hsCRP ≥2mg/L) compared with controls
- reduced risk for time-to-first Major Adverse Cardiac Event (MACE), defined as cardiovascular death, MI or stroke, by 28% (HR 0.72; 95% CI: [0.51, 1.03]) in all-treated patients compared with controls
- reduced risk for time-to-first MACE by 37% (HF 0.63; 95% CI: [0.39, 1.02]) in patients with inflammation (baseline hsCRP≥2mg/L) compared with controls

Results from three randomized controlled trials of rexlemestrocel-L in class II/III and in end-stage HFrEF with left ventricular assist devices (LVADs) support the hypothesis that rexlemestrocel-L acts by a common mechanism of action to reverse inflammation-related endothelial dysfunction, thereby reducing adverse clinical outcomes across the spectrum of HFrEF patients.

Improvement in LVEF at 12 months in patients with HFrEF may be an appropriate early surrogate endpoint for long term reduction in major adverse cardiovascular events (MACE).

Mesoblast plans to meet with the FDA next quarter under its existing RMAT designation for end-stage HFrEF patients with LVADs to discuss common mechanisms- of-action across the spectrum of HFrEF patients from NYHA class II/III to those with an implanted LVAD, and potential pathway to marketing approval.

FINANCIAL RESULTS FOR THE PERIOD ENDED DECEMBER 31, 2022 (SECOND QUARTER FY2023)

- **Cash reserves** as of December 31, 2022 were US$67.6 million. Up to an additional US$40.0 million may be drawn from existing financing facilities subject to achieving certain milestones.
- **Financing Facilities**, in December 2022 we announced that funds managed by Oaktree Capital Management, L.P. ("Oaktree") extended to Mesoblast the availability of up to an additional US$30 million of its US$90 million five-year facility subject to achieving certain milestones on or before September 30, 2023.
- **Net cash usage** for operating activities was US$16.5 million for the second quarter FY2023. This represents a 9% reduction (US$1.7 million) from the second quarter FY2022, and a 46% reduction (US$14.1 million) from the second quarter FY2021.
- **Revenue** from royalties on sales of TEMCELL® HS Inj.[4] sold in Japan by our licensee for the second quarter FY2023 were US$1.9 million. On a constant currency basis, sales for the second quarter FY2023, were US$2.1 million,[5] compared with US$2.3 million for the second quarter FY2022.
- **Research & Development** expenses reduced by US$2.5 million (25%), down to US$7.7 million for the second quarter FY2023 compared to US$10.2 million for the second quarter FY2022. R&D expenses primarily supported preparations for the remestemcel-L BLA re-submission and preparations for pivotal studies for rexlemestrocel-L, as clinical trial activities for our product candidates are reduced since clinical trial recruitment and data analysis are now complete.

- **Manufacturing expenses** were US$7.9 million for the second quarter FY2023 compared to US$6.6 million for the second quarter FY2022. During the quarter we continued pre-launch manufacturing activities and product testing for remestemcel-L to support the potential commercial launch for SR-aGVHD.

  We expect to recognize the US$30.4 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** expenses reduced by US$1.4 million (18%), down to US$6.4 million for the second quarter FY2023 compared to US$7.8 million for the second quarter FY2022 primarily due to decreased legal and professional fees associated with a one-off adjustment in legal expenses during the period.
- **Remeasurement of Contingent Consideration** recognized gains of US$1.5 million in the second quarter FY2023 reflecting a reduction in future third party payments compared to a loss of US$0.4 million in the second quarter FY2022.
- **Fair value movement of warrants** recognized a loss of US$0.3 million in the second quarter FY2023 compared to a gain of US$2.2 million in the second quarter FY2022.
- **Finance Costs for borrowing arrangements** include US$5.0 million of non-cash expenditure for the second quarter FY2023 comprising accruing interest and borrowing costs.

Loss after tax for the second quarter FY2023 was US$24.5 million compared to US$25.9 million for the second quarter FY2022. The net loss attributable to ordinary shareholders was 3.32 US cents per share for the second quarter FY2023, compared with 4.00 US cents per share for the second quarter FY2022.

Conference Call
There will be a webcast today, beginning at 8.30am AEDT (Tuesday, February 28); 4.30pm ET (Monday, February 27). It can be accessed via: https://webcast.openbriefing.com/msb-qtr-2023/

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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and 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. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology.
2. Axt L, Naumann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantation. Bone Marrow Transplantation.
3. Perin EC. Et al. Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure. *JACC* Vol. 81, No. 9, 2023. https://doi.org/10.1016/j.jacc.2022.11.061
4. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
5. TEMCELL sales by our Licensee are recorded in Japanese Yen before being translated into USD for the purposes of calculating the royalty paid to Mesoblast. Results have been adjusted for the movement of the USD to Japanese Yen exchange rate from 1USD:116.02 Yen for the 3 months ended December 31, 2021 to 1USD:133.70 Yen for the 3 months ended December 31, 2022.
6. Rashidi A et al. Outcomes and predictors of response in steroid-refractory acute graft-versus-host disease: single-center results from a cohort of 203 patients. *Biol Blood Bone Marrow Transplant* 2019; 25(11):2297-2302
7. MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. *Bone Marrow Transplant* 2020; 55(1): 165-171
8. Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. *N Engl J Med* 2020;382:1800-10
9. Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. *Blood.* 2020 May 14; 135(20): 1739–1749

Forward-Looking Statements

This press release 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

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended December 31, 2022	Three Months Ended December 31, 2021	Six Months Ended December 31, 2022	Six Months Ended December 31, 2021
Revenue	2,134	2,383	3,636	5,977
Research & development	(7,683)	(10,198)	(13,430)	(19,526)
Manufacturing commercialization	(7,894)	(6,590)	(12,760)	(14,127)
Management and administration	(6,386)	(7,814)	(13,281)	(13,692)
Fair value remeasurement of contingent consideration	1,520	(351)	5,989	(71)
Fair value remeasurement of warrant liability	(311)	2,152	(712)	2,152
Other operating income and expenses	251	(227)	(253)	(405)
Finance costs	(6,188)	(5,380)	(10,685)	(9,040)
Loss before income tax	**(24,557)**	**(26,025)**	**(41,496)**	**(48,732)**
Income tax benefit/(expense)	71	80	126	142
Loss attributable to the owners of Mesoblast Limited	**(24,486)**	**(25,945)**	**(41,370)**	**(48,590)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(3.32)	(4.00)	(5.78)	(7.50)
Diluted - losses per share	(3.32)	(4.00)	(5.78)	(7.50)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended December 31, 2022	Three Months Ended December 31, 2021	Six Months Ended December 31, 2022	Six Months Ended December 31, 2021
Loss for the period	**(24,486)**	**(25,945)**	**(41,370)**	**(48,590)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Exchange differences on translation of foreign operations	259	166	100	(183)
Items that will not be reclassified to profit and loss				
Financial assets at fair value through other comprehensive income	106	112	192	266
Other comprehensive (loss)/income for the period, net of tax	**365**	**278**	**292**	**83**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(24,121)**	**(25,667)**	**(41,078)**	**(48,507)**

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of December 31, 2022	As of June 30, 2022
Assets		
Current Assets		
Cash & cash equivalents	67,619	60,447
Trade & other receivables	5,115	4,403
Prepayments	5,399	4,987
Total Current Assets	**78,133**	**69,837**
Non-Current Assets		
Property, plant and equipment	1,556	2,045
Right-of-use assets	6,598	7,920
Financial assets at fair value through other comprehensive income	1,949	1,758
Other non-current assets	1,922	1,930
Intangible assets	577,902	578,652
Total Non-Current Assets	**589,927**	**592,305**
Total Assets	**668,060**	**662,142**
Liabilities		
Current Liabilities		
Trade and other payables	22,992	23,079
Provisions	17,853	17,906
Borrowings	5,938	5,017
Lease liabilities	3,860	3,186
Warrant liability	3,933	2,185
Total Current Liabilities	**54,576**	**51,373**
Non-Current Liabilities		
Provisions	8,998	12,523
Borrowings	96,984	91,617
Lease liabilities	5,000	7,085
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**113,482**	**113,725**
Total Liabilities	**168,058**	**165,098**
Net Assets	**500,002**	**497,044**
Equity		
Issued Capital	1,207,714	1,165,309
Reserves	72,574	70,651
(Accumulated losses)/retained earnings	(780,286)	(738,916)
Total Equity	**500,002**	**497,044**

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Six Months Ended December 31, 2022	2021
Cash flows from operating activities		
Commercialization revenue received	3,667	5,531
Government grants and tax incentives received	18	24
Payments to suppliers and employees (inclusive of goods and services tax)	(34,633)	(41,977)
Interest received	207	4
Net cash (outflows) in operating activities	**(30,741)**	**(36,418)**
Cash flows from investing activities		
Investment in fixed assets	(187)	(103)
Payments for intellectual property	(50)	(26)
Net cash (outflows) in investing activities	**(237)**	**(129)**
Cash flows from financing activities		
Proceeds from borrowings	—	51,919
Repayment of borrowings	—	(55,458)
Payment of transaction costs from borrowings	(217)	(5,453)
Interest and other costs of finance paid	(2,807)	(2,951)
Proceeds from issue of shares	45,065	209
Proceeds from issue of warrants	—	8,081
Payments for share issue costs	(2,646)	(216)
Payments for lease liabilities	(1,109)	(1,214)
Net cash inflows/(outflows) by financing activities	**38,286**	**(5,083)**
Net increase/(decrease) in cash and cash equivalents	7,308	(41,630)
Cash and cash equivalents at beginning of period	60,447	136,881
FX gain/(losses) on the translation of foreign bank accounts	(136)	(402)
Cash and cash equivalents at end of period	**67,619**	**94,849**